



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

November 21, 2011

MEMORANDUM

Subject: Efficacy Review for Maguard 5626; EPA File Symbol 10324-ERU; DP Barcode: D392898.

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Applicant: Mason Chemical Company
721 W. Algonquin Road
Arlington Heights, IL 60005

Formulation from the Label:

<u>Active Ingredient</u>	<u>% by wt.</u>
Peroxyacetic Acid.....	5.9 %
Hydrogen Peroxide	27.3 %
<u>Inert Ingredients:</u>	<u>66.8 %</u>
Total	100.0 %

I. BACKGROUND

The product, Maguard 5626 (EPA File Symbol 10324-ERU), is a new product. The applicant requested to register the product for use as a disinfectant (bactericide, fungicide, virucide), sanitizer, and deodorizer on hard, non-porous surfaces in commercial, institutional, industrial, food processing, animal care, and hospital or medical environments. The product also may be used in various industrial applications. The label states that the product is an effective disinfectant in the presence of 400 ppm hard water and 5% blood serum. The label states that the product is an effective sanitizer when a solution is prepared in water of up to 500 ppm hardness as CaCO_3 . Studies were conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, in Eagan, MN 55121.

This data package contained a letter from the applicant's representative to EPA (dated July 27, 2011), EPA Form 8570-4 (Basic and Alternative Formulations' Confidential Statements of Formula – dated 11/21/2011), fifty three studies (MRID 485552-09 through 485552-61), Statements of No Data Confidentiality Claims for all fifty three studies, and the proposed label (dated 11/21/2011).

II. USE DIRECTIONS

The product is designed for disinfecting hard, non-porous surfaces, including: appliance exteriors, bathroom fixtures, bed frames, cages, carts, chairs, coolers, counter tops, feeding equipment, floors, furniture, kennel runs, operating tables, racks, shelves, sinks, tables, and walls. In addition, the product is designed for sanitizing pre-cleaned, hard, non-porous surfaces, including: conveyors, drinking utensils, eating utensils, equipment, evaporators, filters, food preparation utensils, pasteurizers, pipelines, saws, slicers, tableware, tanks, and vats. The proposed label indicates that the product may be used on hard, non-porous surfaces, including: glass, glazed porcelain, linoleum, plastic, stainless steel, tile, and vinyl. Directions on the proposed label provide the following information regarding preparation and use of the product:

As a disinfectant in non-medical facilities: Prepare a use solution by adding 1.5 ounces of the product and 5 gallons of water (a 1:320 dilution). Apply use solution with a brush, cloth, mop, sponge, or mechanical spray device, coarse pump, or trigger spray device thoroughly wetting surfaces as required. Treated surfaces must remain wet for 10 minutes. Rinse or allow to air dry. For heavily soiled areas, a preliminary cleaning is required.

As a disinfectant in institutions: Prepare a use solution by adding 2 ounces of the product and 5 gallons of water (a 1:427 dilution). Apply use solution with a brush, cloth, mop, sponge, or mechanical spray device, coarse pump, or trigger spray device thoroughly wetting surfaces as required. Treated surfaces must remain wet for 10 minutes. Rinse or allow to air dry. For heavily soiled areas, a preliminary cleaning is required.

As a sanitizer: Remove gross food particles. Wash with a detergent solution. Rinse with potable water. Prepare a use solution by adding 1-2 ounces of the product and 6 gallons of water (73-146 ppm active; a 1:768-1:384 dilution). Apply use solution to surfaces, using immersion, coarse spray, or circulation techniques. All surfaces must be exposed for at least 30 seconds. Drain excess solution.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments: The effectiveness of disinfectants for use on hard surfaces in hospital or medical environments must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray products). Sixty carriers must be tested with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old, against *Salmonella enterica* (ATCC 10708; formerly *Salmonella choleraesuis*), *Staphylococcus aureus* (ATCC 6538), and *Pseudomonas aeruginosa* (ATCC 15442). To support products labeled as "disinfectants," killing on 59 out of 60 carriers is required to provide effectiveness at the 95% confidence level.

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments (Additional Bacteria): Effectiveness of disinfectants against specific bacteria other than those named in the AOAC Use-Dilution Method, AOAC Germicidal Spray Products as Disinfectants Method, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products as Disinfectants Method. Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different product lots. To support products labeled as "disinfectants" for specific bacteria (other than those bacteria named in the above test methods), killing of the specific microorganism on all carriers is required.

Disinfectants for Use as Fungicides (Against Pathogenic Fungi, Using a Modified AOAC Use-Dilution Method): The effectiveness of liquid disinfectants against specific pathogenic fungi must be supported by efficacy data using an appropriate test. The AOAC Use-Dilution Method may be modified to conform with the appropriate elements in the AOAC Fungicidal Test. The inoculum in the test must be modified to provide a concentration of at least 10^6 conidia per carrier. Ten carriers on each of 2 product samples representing 2 different product lots must be employed in the test. Killing of the specific pathogenic fungi on all carriers is required.

Note: As an interim policy, EPA is accepting studies with dried carrier counts that are at least 10^4 for *Trichophyton mentagrophytes*, *Aspergillus niger*, and *Candida albicans*. EPA recognizes laboratories are experiencing problems in maintaining dried carrier counts at the 10^6 level. This interim policy will be in effect until EPA determines that the laboratories are able to achieve consistent carrier counts at the 10^6 level.

Virucides: The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When

cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

Virucides – Novel Virus Protocol Standards: To ensure that a virus protocol has been adequately validated, data should be provided from at least 2 independent laboratories for each product tested (i.e., 2 product lots per laboratory).

Sanitizing Rinses (For Previously Cleaned, Food Contact Surfaces): Sanitizing rinses may be formulated with quaternary ammonium compounds, chlorinated trisodium phosphate, or anionic detergent-acid formulations. The effectiveness of such sanitizing rinses for previously cleaned, food contact surfaces must be substantiated by data derived from the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method. Data from the test on 1 sample from each of 3 different product lots, one of which is at least 60 days old against *Escherichia coli* (ATCC 11229) and *Staphylococcus aureus* (ATCC 6538) are required. When the effectiveness of the product in hard water is made, all required data must be developed at the hard water tolerance claimed. Acceptable results must demonstrate a 99.999% reduction in the number of microorganisms within 30 seconds. The results must be reported according to the actual count and the percentage reduction over the control. Furthermore, counts on the number controls for the product should fall between 75 and $125 \times 10^6/\text{mL}$ for percent reductions to be considered valid. Label directions for use must state that a contact time of at least 1 minute is required for sanitization. A potable water rinse is not required (to remove the use solution from the treated surface) for products cleared for use on food contact surfaces under the Federal Food, Drug, and Cosmetic Act. Label directions must recommend a potable water rinse (to remove the use solution from the treated surface) under any other circumstances.

Sanitizing Rinses (For Previously Cleaned, Food Contact Surfaces; Additional Bacteria): There are cases where an applicant requests to make claims of effectiveness against additional bacteria for a product that is already registered as a sanitizing rinse for previously cleaned, food contact surfaces. EPA staff indicated that the DIS/TSS-5 standards are silent on this matter and that confirmatory test standards would apply. EPA staff indicated that, for sanitizing rinses for previously cleaned, food contact surfaces, 2 product samples, representing 2 different product lots, must be tested against each additional microorganism. Results must show a bacterial reduction of at least 99.999% in the number of microorganisms within 30 seconds. The results must be reported according to the actual count and the percentage reduction over the control.

Furthermore, according to information in the above AOAC test method itself, counts on number controls for the product should fall between 75 and $125 \times 10^6/\text{mL}$ for percent reductions to be considered valid. Label directions for use, however, must state that a contact time of at least 1 minute is required for sanitization.

Supplemental Claims: An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum. On a product label, the hard water tolerance level may differ with the level of antimicrobial activity (e.g., sanitizer vs. disinfectant) claimed. To establish efficacy in hard water, all microorganisms (i.e., bacteria, fungi, viruses) claimed to be controlled must be tested by the appropriate Recommended Method at the same hard water tolerance level.

IV. BRIEF DESCRIPTION OF THE DATA

1. MRID 485552-09 "AOAC Use-Dilution Method, Test Organism: *Staphylococcus aureus* (ATCC 6538)" for Maguard PAA-5%, by Lynsey Wieland. Study conducted at ATS Labs. Study completion date – March 29, 2010. Project Number A09199.

This study was conducted against *Staphylococcus aureus* (ATCC 6538). One lot (Lot A) of the product, Maguard PAA-5%, was tested using ATS Laboratory Protocol No. MC03022310.UD.1 (copy provided). The product lot tested was at least 60 days old at the time of testing. A use solution was prepared by adding 2.00 mL of the product and 852 mL of 400 ppm AOAC synthetic hard water (titrated at 394 ppm; a 1:427 dilution). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Sixty (60) stainless steel penicylinder carriers were immersed for 15 minutes in a 48-54 hour old suspension of test organism, at a ratio of 1 carrier per 1 mL broth. The carriers were dried for 40 minutes at 35-37°C at 47% relative humidity. Each carrier was placed in 10.0 mL of the use solution for 10 minutes at 20.0°C. Following exposure, individual carriers were transferred to 10 mL of Letheen Broth with 0.1% sodium thiosulfate and 0.01% Catalase to neutralize. All subcultures were incubated for 46.5 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

2. MRID 485552-10 "AOAC Use-Dilution Method, Test Organism: *Staphylococcus aureus* (ATCC 6538)" for Maguard PAA-5%, by Lynsey Wieland. Study conducted at ATS Labs. Study completion date – March 30, 2010. Project Number A09200.

This study was conducted against *Staphylococcus aureus* (ATCC 6538). One lot (Lot B) of the product, Maguard PAA-5%, was tested using ATS Laboratory Protocol No. MC03022310.UD.2 (copy provided). A use solution was prepared by adding 2.00 mL of the product and 852 mL of 400 ppm AOAC synthetic hard water (titrated at 394 ppm; a 1:427 dilution). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Sixty (60) stainless steel penicylinder carriers were immersed for 15 minutes in a 48-54 hour old suspension of test organism, at a ratio of 1 carrier per 1 mL broth. The carriers were dried for 40 minutes at 35-37°C at 47% relative humidity. Each carrier was placed in 10.0 mL of the use solution for 10 minutes at 20.0°C. Following exposure, individual carriers were transferred to 10 mL of Letheen Broth with 0.1% sodium thiosulfate and 0.01% Catalase to neutralize. All subcultures were incubated for 47.25 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

3. MRID 485552-11 "AOAC Use-Dilution Method, Test Organism: *Staphylococcus aureus* (ATCC 6538)" for Maguard PAA-5%, by Lynsey Wieland. Study conducted at ATS Labs. Study completion date – April 1, 2010. Project Number A09201.

This study was conducted against *Staphylococcus aureus* (ATCC 6538). One lot (Lot C) of the product, Maguard PAA-5%, was tested using ATS Laboratory Protocol No. MC03022310.UD.3 (copy provided). A use solution was prepared by adding 2.00 mL of the product and 852 mL of 400 ppm AOAC synthetic hard water (titrated at 394 ppm; a 1:427 dilution). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Sixty (60) stainless steel penicylinder carriers were immersed for 15 minutes in a 48-54 hour old suspension of test organism, at a ratio of 1 carrier per 1 mL broth. The carriers were dried for 40 minutes at 35-37°C at 47% relative humidity. Each carrier was placed in 10.0 mL of the use

solution for 10 minutes at 20.0°C. Following exposure, individual carriers were transferred to 10 mL of Lethen Broth with 0.1% sodium thiosulfate and 0.01% Catalase to neutralize. All subcultures were incubated for 47.25 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

4. MRID 485552-12 "AOAC Use-Dilution Method, Test Organism: *Salmonella enterica* (ATCC 10708)" for Maguard PAA-5%, by Joshua Luedtke. Study conducted at ATS Labs. Study completion date – March 31, 2010. Project Number A09205.

This study was conducted against *Salmonella enterica* (ATCC 10708). One lot (Lot A) of the product, Maguard PAA-5%, was tested using ATS Laboratory Protocol No. MC03022310.UD.7 (copy provided). The product lot tested was at least 60 days old at the time of testing. A use solution was prepared by adding 2.00 mL of the product and 852 mL of 400 ppm AOAC synthetic hard water (titrated at 390 ppm; a 1:427 dilution). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Sixty (60) stainless steel penicylinder carriers were immersed for 15 minutes in a 48-54 hour old suspension of test organism, at a ratio of 1 carrier per 1 mL broth. The carriers were dried for 40 minutes at 35-37°C at 20.84% relative humidity. Each carrier was placed in 10.0 mL of the use solution for 10 minutes at 19.0°C. Following exposure, individual carriers were transferred to 10 mL of Lethen Broth with 0.1% sodium thiosulfate and 0.01% Catalase to neutralize. All subcultures were incubated for ~50 hours at 35-37°C. The subcultures were stored for 2 days at 2-8°C prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

5. MRID 485552-13 "AOAC Use-Dilution Method, Test Organism: *Salmonella enterica* (ATCC 10708)" for Maguard PAA-5%, by Joshua Luedtke. Study conducted at ATS Labs. Study completion date – March 31, 2010. Project Number A09207.

This study was conducted against *Salmonella enterica* (ATCC 10708). One lot (Lot B) of the product, Maguard PAA-5%, was tested using ATS Laboratory Protocol No. MC03022310.UD.9 (copy provided). A use solution was prepared by adding 2.00 mL of the product and 852 mL of 400 ppm AOAC synthetic hard water (titrated at 390 ppm; a 1:427 dilution). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Sixty (60) stainless steel penicylinder carriers were immersed for 15 minutes in a 48-54 hour old suspension of test organism, at a ratio of 1 carrier per 1 mL broth. The carriers were dried for 40 minutes at 35-37°C at 20.84% relative humidity. Each carrier was placed in 10.0 mL of the use solution for 10 minutes at 19.0°C. Following exposure, individual carriers were transferred to 10 mL of Lethen Broth with 0.1% sodium thiosulfate and 0.01% Catalase to neutralize. All subcultures were incubated for ~50 hours at 35-37°C. The subcultures were stored for 2 days at 2-8°C prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

6. MRID 485552-14 "AOAC Use-Dilution Method, Test Organism: *Salmonella enterica* (ATCC 10708)" for Maguard PAA-5%, by Joshua Luedtke. Study conducted at ATS Labs. Study completion date – April 1, 2010. Project Number A09206.

This study was conducted against *Salmonella enterica* (ATCC 10708). One lot (Lot C) of the product, Maguard PAA-5%, was tested using ATS Laboratory Protocol No. MC03022310.UD.8 (copy provided). A use solution was prepared by adding 2.00 mL of the product and 852 mL of 400 ppm AOAC synthetic hard water (titrated at 390 ppm; a 1:427 dilution). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Sixty (60) stainless steel penicylinder carriers were immersed for 15 minutes in a 48-54 hour old suspension of test organism, at a ratio of 1 carrier per 1 mL broth. The carriers were dried for 40 minutes at 35-37°C at 20.84% relative humidity. Each carrier was placed in 10.0 mL of the use solution for 10 minutes at 19.0°C. Following exposure, individual carriers were transferred to 10 mL of Lethen Broth with 0.1% sodium thiosulfate and 0.01% Catalase to neutralize. All subcultures were incubated for ~50 hours at 35-37°C. The subcultures were stored for 2 days at 2-8°C prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

7. MRID 485552-15 "AOAC Use-Dilution Method, Test Organism: *Pseudomonas aeruginosa* (ATCC 15442)" for Maguard PAA-5%, by Jill Ruhme. Study conducted at ATS Labs. Study completion date – April 29, 2010. Project Number A09330.

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442). One lot (Lot A) of the product, Maguard PAA-5%, was tested using ATS Laboratory Protocol No. MC03033110.UD.1 (copy provided). The product lot tested was at least 60 days old at the time of testing. [See Study Information sheet of laboratory report.] A use solution was prepared by adding 2.00 mL of the product and 638 mL of 400 ppm AOAC synthetic hard water (titrated at 390 ppm; a 1:320 dilution). A culture of the challenge microorganism was prepared in accordance with the published AOAC methods. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Sixty (60) stainless steel penicylinder carriers were immersed for 15 minutes in a 48-54 hour old suspension of test organism, at a ratio of 1 carrier per 1 mL broth. The carriers were dried for 40 minutes at 35-37°C at 41% relative humidity. Each carrier was placed in 10.0 mL of the use solution for 10 minutes at 20.0°C. Following exposure, individual carriers were transferred to 10 mL of Lethen Broth with 0.1% sodium thiosulfate and 0.01% Catalase to neutralize. All subcultures were incubated for 48±4 hours at 35-37°C. The subcultures were stored for 1 day at 2-8°C prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

8. MRID 485552-16 "AOAC Use-Dilution Method, Test Organism: *Pseudomonas aeruginosa* (ATCC 15442)" for Maguard PAA-5%, by Joshua Luedtke. Study conducted at ATS Labs. Study completion date – April 27, 2010. Project Number A09328.

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442). One lot (Lot B) of the product, Maguard PAA-5%, was tested using ATS Laboratory Protocol No. MC03033110.UD.2 (copy provided). A use solution was prepared by adding 2.00 mL of the product and 638 mL of 400 ppm AOAC synthetic hard water (titrated at 390 ppm; a 1:320 dilution). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Sixty (60) stainless steel penicylinder carriers were immersed for 15 minutes in a 48-54 hour old suspension of test organism, at a ratio of 1 carrier per 1.0 mL broth. The carriers were dried for 40 minutes at 35-37°C at 41% relative humidity. Each carrier was placed in 10.0 mL of use solution for 10 minutes at 20.0°C. Following exposure, individual carriers were transferred to 10

mL of Letheen Broth with 0.1% sodium thiosulfate and 0.01% Catalase to neutralize. All subcultures were incubated for ~44 hours at 35-37°C. The subcultures were stored for 2 days at 2-8°C prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

9. MRID 485552-17 "AOAC Use-Dilution Method, Test Organism: *Pseudomonas aeruginosa* (ATCC 15442)" for Maguard PAA-5%, by Jill Ruhme. Study conducted at ATS Labs. Study completion date – April 29, 2010. Project Number A09329.

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442). One lot (Lot C) of the product, Maguard PAA-5%, was tested using ATS Laboratory Protocol No. MC03033110.UD.3 (copy provided). A use solution was prepared by adding 2.00 mL of the product and 638 mL of 400 ppm AOAC synthetic hard water (titrated at 390 ppm; a 1:320 dilution). A culture of the challenge microorganism was prepared in accordance with the published AOAC methods. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Sixty (60) stainless steel penicylinder carriers were immersed for 15 minutes in a 48-54 hour old suspension of test organism, at a ratio of 1 carrier per 1 mL broth. The carriers were dried for 40 minutes at 35-37°C at 41% relative humidity. Each carrier was placed in 10.0 mL of the use solution for 10 minutes at 20.0°C. Following exposure, individual carriers were transferred to 10 mL of Letheen Broth with 0.1% sodium thiosulfate and 0.01% Catalase to neutralize. All subcultures were incubated for 48±4 hours at 35-37°C. The subcultures were stored for 1 day at 2-8°C prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

10. MRID 485552-18 "AOAC Use-Dilution Method, Test Organism: Vancomycin Resistant *Enterococcus faecalis* -VRE (ATCC 51575)" for Maguard PAA-5%, by Becky Lien. Study conducted at ATS Labs. Study completion date – June 17, 2010. Project Number A09546.

This study was conducted against Vancomycin Resistant *Enterococcus faecalis* (ATCC 51575). Two lots (Lots B and C) of the product, Maguard PAA-5%, were tested using ATS Laboratory Protocol No. MC03051310.UD.4 (copy provided). Use solutions were prepared by adding 2.00 mL of the product and 852 mL of 400 ppm AOAC synthetic hard water (titrated at 404 ppm; a 1:427 dilution). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers per product lot were immersed for 15 minutes in a 48-54 hour old suspension of test organism, at a ratio of 1 carrier per 1.0 mL broth. The carriers were dried for 40 minutes at 25-30°C at 63% relative humidity. Each carrier was placed in 10.0 mL of the use solution for 10 minutes at 19.0°C. Following exposure, individual carriers were transferred to 10 mL of Letheen Broth with 0.1% sodium thiosulfate and 0.01% Catalase to neutralize. All subcultures were incubated for 48 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, neutralization confirmation, and antibiotic resistance.

Note: Antibiotic resistance of Vancomycin Resistant *Enterococcus faecalis* (ATCC 51575) was verified on a representative culture. The laboratory performed a Kirby Bauer Susceptibility assay. *Staphylococcus aureus* (ATCC 25923) was the control organism. The measured zone of inhibition (i.e., 6 mm) confirmed antibiotic resistance of Vancomycin Resistant *Enterococcus faecalis* (ATCC 51575) to vancomycin. See page 9 and Table 5 of the laboratory report.

Note: Protocol deviations/amendments reported in the study were reviewed.

11. MRID 485552-19 "AOAC Use-Dilution Method, Test Organism: Vancomycin Intermediate Resistant *Staphylococcus aureus* - VISA (HIP 5836)" for Maguard PAA-5%, by Anne Stemper. Study conducted at ATS Labs. Study completion date – June 29, 2010. Project Number A09550.

This study was conducted against Vancomycin Intermediate Resistant *Staphylococcus aureus* (HIP 5836). Two lots (Lots B and C) of the product, Maguard PAA-5%, were tested using ATS Laboratory Protocol No. MC03051310.UD.11 (copy provided). Use solutions were prepared by adding 1.00 mL of the product and 426 mL of 400 ppm AOAC synthetic hard water (titrated at 392 ppm; a 1:427 dilution). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers per product lot were immersed for 15 minutes in a 2 day old suspension of test organism, at a ratio of 1 carrier per 1 mL broth. The carriers were dried for 40 minutes at 35-37°C at 41% relative humidity. Each carrier was placed in 10.0 mL of the use solution for 10 minutes at 19.0°C. Following exposure, individual carriers were transferred to 10 mL of Lethen Broth with 0.1% sodium thiosulfate and 0.01% Catalase to neutralize. All subcultures were incubated for 48±4 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, neutralization confirmation, and antibiotic resistance.

Note: The laboratory reported a failed study set up on June 2, 2010. In the study, unexpected results were obtained in the antibiotic resistance control. The laboratory did not accept the assay. These data were not used to evaluate efficacy of the product. Testing was repeated on June 16, 2010, with modifications to the preparation of the challenge microorganism. See page 8 and Attachment I of the laboratory report.

Note: The antimicrobial susceptibility pattern of Vancomycin Intermediate Resistant *Staphylococcus aureus* (HIP 5836) was verified on a representative culture. The laboratory performed an E test Method assay, using a vancomycin strip. *Staphylococcus aureus* (ATCC 29213) served as the control organism. The Minimum Inhibitory Concentration (MIC) values were determined. The MIC values confirmed the antimicrobial susceptibility pattern of Vancomycin Intermediate Resistant *Staphylococcus aureus* (HIP 5836). See page 9 and Table 5 of the laboratory report.

Note: Protocol deviations/amendments reported in the study were reviewed.

12. MRID 485552-20 "AOAC Use-Dilution Method, Test Organism: Community Acquired Methicillin Resistant *Staphylococcus aureus* - CA-MRSA (NARSA NRS123) (Genotype USA400)" for Maguard PAA-5%, by Lynsey Wieland. Study conducted at ATS Labs. Study completion date – August 25, 2010. Project Number A09970.

This study was conducted against Community Acquired Methicillin Resistant *Staphylococcus aureus* (NARSA NRS123) (Genotype USA400; obtained from the NARSA Contracts Administrator, Focus Technologies, Inc., Herndon, VA). Two lots (Lots B and C) of the product, Maguard PAA-5%, were tested using ATS Laboratory Protocol No. MC03062910.UD.4 (copy provided). Use solutions were prepared by adding 2.00 mL of the product and 638 mL of 400 ppm AOAC synthetic hard water (titrated at 404 ppm; a 1:320 dilution). Fetal bovine serum

was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers per product lot were immersed for 15 minutes in a 48-54 hour old suspension of test organism, at a ratio of 1 carrier per 1.0 mL broth. The carriers were dried for 40 minutes at 35-37°C at 44.76% relative humidity. Each carrier was placed in 10.0 mL of the use solution for 10 minutes at 19.0°C. Following exposure, individual carriers were transferred to 10 mL of Letheen Broth with 0.1% sodium thiosulfate and 0.01% Catalase to neutralize. All subcultures were incubated for 44 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, neutralization confirmation, and antibiotic resistance.

Note: Antibiotic resistance of Community Acquired Methicillin Resistant *Staphylococcus aureus* (NARSA NRS123) (Genotype USA400) was verified on a representative culture. The laboratory performed a Kirby Bauer Susceptibility assay. *Staphylococcus aureus* (ATCC 25923) was the control organism. The measured zone of inhibition (i.e., 6 mm) confirmed antibiotic resistance of Community Acquired Methicillin Resistant *Staphylococcus aureus* (NARSA NRS123) (Genotype USA400) to oxacillin. See page 9 and Table 5 of the laboratory report.

13. MRID 485552-21 "AOAC Use-Dilution Method, Test Organism: *Bordetella bronchiseptica* (ATCC 10580)" for Maguard PAA-5%, by Jill Ruhme. Study conducted at ATS Labs. Study completion date – June 24, 2010. Project Number A09541.

This study was conducted against *Bordetella bronchiseptica* (ATCC 10580). Two lots (Lots B and C) of the product, Maguard PAA-5%, were tested using ATS Laboratory Protocol No. MC03051310.UD.1 (copy provided). Use solutions were prepared by adding 1.00 mL of the product and 426 mL of 400 ppm AOAC synthetic hard water (titrated at 404 ppm; a 1:427 dilution). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers per product lot were immersed for 15 minutes in a 48-54 hour old suspension of test organism, at a ratio of 1 carrier per 1 mL broth. The carriers were dried for 40 minutes at 35-37°C at 38% relative humidity. Each carrier was placed in 10.0 mL of the use solution for 10 minutes at 18.0°C. Following exposure, individual carriers were transferred to 10 mL of Letheen Broth with 0.1% sodium thiosulfate and 0.01% Catalase to neutralize. All subcultures were incubated for ~46 hours at 35-37°C. The subcultures were stored for 1 day at 2-8°C prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

Note: Protocol deviations/amendments reported in the study were reviewed.

14. MRID 485552-22 "AOAC Use-Dilution Method, Test Organism: *Corynebacterium ammoniagenes* (ATCC 6872)" for Maguard PAA-5%, by Anne Stemper. Study conducted at ATS Labs. Study completion date – June 16, 2010. Project Number A09545.

This study was conducted against *Corynebacterium ammoniagenes* (ATCC 6872). Two lots (Lots B and C) of the product, Maguard PAA-5%, were tested using ATS Laboratory Protocol No. MC03051310.UD.2 (copy provided). Use solutions were prepared by adding 1.00 mL of the product and 426 mL of 400 ppm AOAC synthetic hard water (titrated at 408 ppm; a 1:427 dilution). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers per product lot were immersed for 15 minutes in a 48-54 hour old suspension of test organism, at a ratio of 1 carrier per 1 mL broth. The carriers

were dried for 40 minutes at 35-37°C at 43% relative humidity. Each carrier was placed in 10.0 mL of the use solution for 10 minutes at 19.0°C. Following exposure, individual carriers were transferred to 10 mL of Letheen Broth with 0.1% sodium thiosulfate and 0.01% Catalase to neutralize. Carriers were transferred from primary subculture tubes into individual secondary subculture tubes containing 10 mL of tryptic soy broth at least 30 minutes following the first transfer. All subcultures were incubated for ~47 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

Note: Protocol deviations/amendments reported in the study were reviewed.

15. MRID 485552-23 "AOAC Use-Dilution Method - Quantitated, Test Organism: *Campylobacter jejuni* (ATCC 29428)" for Maguard PAA-5%, by Anne Stemper. Study conducted at ATS Labs. Study completion date – August 30, 2010. Project Number A09952.

This study was conducted against *Campylobacter jejuni* (ATCC 29428). Two lots (Lot B and C) of the product, Maguard PAA-5%, were tested using ATS Laboratory Protocol No. MC03062910.UD.1 (copy provided). Use solutions were prepared by adding 2.00 mL of the product and 638 mL of 400 ppm AOAC synthetic hard water (titrated at 404 ppm; a 1:320 dilution). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers per product lot were immersed for 15 minutes in a 5 day old suspension of test organism, at a ratio of 1 carrier per 1.0 mL broth. The carriers were dried for 40 minutes at 35-37°C at 63% relative humidity. Each carrier was placed in 10.0 mL of the use solution for 10 minutes at 22.0°C. Following exposure, individual carriers were transferred to 10 mL of Letheen Broth with 0.1% sodium thiosulfate and 0.01% Catalase to neutralize. The tubes containing neutralizer were gently shaken after addition of the carriers, as specified in the AOAC method. The contents of each subculture container were individually transferred to the surface of a pre-wetted filter membrane and filtered using a vacuum pump. Each filter membrane was washed with sterile saline. Each filter membrane was aseptically transferred to a plate containing tryptic soy agar with 5% sheep's blood agar. All subcultures were incubated for 2 days at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

16. MRID 485552-24 "AOAC Use-Dilution Method, Test Organism: *Klebsiella pneumoniae* (ATCC 4352)" for Maguard PAA-5%, by Lynsey Wieland. Study conducted at ATS Labs. Study completion date – August 24, 2010. Project Number A09968.

This study was conducted against *Klebsiella pneumoniae* (ATCC 4352). Two lots (Lots B and C) of the product, Maguard PAA-5%, were tested using ATS Laboratory Protocol No. MC03062910.UD.2 (copy provided). Use solutions were prepared by adding 2.00 mL of the product and 638 mL of 400 ppm AOAC synthetic hard water (titrated at 404 ppm; a 1:320 dilution). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers per product lot were immersed for 15 minutes in a 48-54 hour old suspension of test organism, at a ratio of 1 carrier per 1.0 mL broth. The carriers were dried for 40 minutes at 35-37°C at 40.98% relative humidity. Each carrier was placed in 10.0 mL of the use solution for 10 minutes at 22.0°C. Following exposure, individual carriers were transferred to 10 mL of Letheen Broth with 0.1% sodium thiosulfate and 0.01% Catalase to neutralize. All subcultures were incubated for ~45 hours at 35-37°C. Following incubation, the

subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

17. MRID 485552-25 "AOAC Use-Dilution Method, Test Organism: *Listeria monocytogenes* (ATCC 19117)" for Maguard PAA-5%, by Matthew Sathe. Study conducted at ATS Labs. Study completion date – June 22, 2010. Project Number A09547.

This study was conducted against *Listeria monocytogenes* (ATCC 19117). Two lots (Lots B and C) of the product, Maguard PAA-5%, were tested using ATS Laboratory Protocol No. MC03051310.UD.6 (copy provided). Use solutions were prepared by adding 2.00 mL of the product and 852 mL of 400 ppm AOAC synthetic hard water (titrated at 404 ppm; a 1:427 dilution). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers per product lot were immersed for 15 minutes in a 52.75 hour old suspension of test organism, at a ratio of 1 carrier per 1.0 mL broth. The carriers were dried for 40 minutes at 35-37°C at 37.21% relative humidity. Each carrier was placed in 10.0 mL of the use solution for 10 minutes at 18.0°C. Following exposure, individual carriers were transferred to 10 mL of Letheen Broth with 0.1% sodium thiosulfate and 0.01% Catalase to neutralize. All subcultures were incubated for 47 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

Note: Protocol deviations/amendments reported in the study were reviewed.

18. MRID 485552-26 "AOAC Use-Dilution Method, Test Organism: *Shigella sonnei* (ATCC 25931)" for Maguard PAA-5%, by Matthew Sathe. Study conducted at ATS Labs. Study completion date – June 23, 2010. Project Number A09549.

This study was conducted against *Shigella sonnei* (ATCC 25931). Two lots (Lots B and C) of the product, Maguard PAA-5%, were tested using ATS Laboratory Protocol No. MC03051310.UD.8 (copy provided). Use solutions were prepared by adding 2.00 mL of the product and 852 mL of 400 ppm AOAC synthetic hard water (titrated at 404 ppm; a 1:427 dilution). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers per product lot were immersed for 15 minutes in a 52.75 hour old suspension of test organism, at a ratio of 1 carrier per 1.0 mL broth. The carriers were dried for 40 minutes at 35-37°C at 37.21% relative humidity. Each carrier was placed in 10.0 mL of the use solution for 10 minutes at 18.0°C. Following exposure, individual carriers were transferred to 10 mL of Letheen Broth with 0.1% sodium thiosulfate and 0.01% Catalase to neutralize. All subcultures were incubated for 46.75 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

Note: Protocol deviations/amendments reported in the study were reviewed.

19. MRID 485552-27 "AOAC Use-Dilution Method, Test Organism: *Salmonella typhi* (ATCC 6539)" for Maguard PAA-5%, by Joshua Luedtke. Study conducted at ATS Labs. Study completion date – June 11, 2010. Project Number A09548.

This study was conducted against *Salmonella typhi* (ATCC 6539). Two lots (Lots B and C) of the product, Maguard PAA-5%, were tested using ATS Laboratory Protocol No. MC03051310.UD.7 (copy provided). Use solutions were prepared by adding 1.00 mL of the

product and 426 mL of 400 ppm AOAC synthetic hard water (titrated at 400 ppm; a 1:427 dilution). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers per product lot were immersed for 15 minutes in a 48-54 hour old suspension of test organism, at a ratio of 1 carrier per 1.0 mL broth. The carriers were dried for 40 minutes at 35-37°C at 42% relative humidity. Each carrier was placed in 10.0 mL of the use solution for 10 minutes at 18.0°C. Following exposure, individual carriers were transferred to 10 mL of Lethen Broth with 0.1% sodium thiosulfate and 0.01% Catalase to neutralize. All subcultures were incubated for 48±4 hours at 35-37°C. The subcultures were stored for 2 days at 2-8°C prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

Note: Protocol deviations/amendments reported in the study were reviewed.

20. MRID 485552-28 "AOAC Use-Dilution Method, Test Organism: *Escherichia coli* O157:H7 (ATCC 35150)" for Maguard PAA-5%, by Becky Lien. Study conducted at ATS Labs. Study completion date – June 10, 2010. Project Number A09536.

This study was conducted against *Escherichia coli* O157:H7 (ATCC 35150). Two lots (Lots B and C) of the product, Maguard PAA-5%, were tested using ATS Laboratory Protocol No. MC03051310.UD.3 (copy provided). Use solutions were prepared by adding 2.00 mL of the product and 852 mL of 400 ppm AOAC synthetic hard water (titrated at 400 ppm; a 1:427 dilution). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers per product lot were immersed for 15 minutes in a 48-54 hour old suspension of test organism, at a ratio of 1 carrier per 1.0 mL broth. The carriers were dried for 40 minutes at 35-37°C at 42% relative humidity. Each carrier was placed in 10.0 mL of the use solution for 10 minutes at 18.0°C. Following exposure, individual carriers were transferred to 10 mL of Lethen Broth with 0.1% sodium thiosulfate and 0.01% Catalase to neutralize. All subcultures were incubated for 46 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

Note: Protocol deviations/amendments reported in the study were reviewed.

21. MRID 485552-29 "Fungicidal Use-Dilution Method, Test Organism: *Trichophyton mentagrophytes* (ATCC 9533)" for Maguard PAA-5%, by Jill Ruhme. Study conducted at ATS Labs. Study completion date – June 24, 2010. Project Number A09520.

This study was conducted against *Trichophyton mentagrophytes* (ATCC 9533). Two lots (Lot B and C) of the product, Maguard PAA-5%, were tested using ATS Laboratory Protocol No. MC03051310.FUD (copy provided). Use solutions were prepared by adding 1.00 mL of the product and 426 mL of 400 ppm AOAC synthetic hard water (titrated at 400 ppm; a 1:427 dilution). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers per product lot were immersed for 15 minutes in a 10-day old suspension of test organism, at a ratio of 1 carrier per 1 mL suspension. The carriers were dried for 40 minutes at 35-37°C at 41% relative humidity. Each carrier was placed in 10.0 mL of the use solution for 10 minutes at 19.0°C. Following exposure, individual carriers were transferred to 10 mL of Sabouraud Dextrose Broth with 0.1% sodium thiosulfate and 0.01% Catalase to neutralize. Carriers were transferred from primary subculture tubes into individual

secondary subculture tubes containing 10 mL of Sabouraud Dextrose Broth with 0.07% Lecithin and 0.5% Tween 80 at least 30 minutes following the first transfer. All subcultures were incubated for 10 days at 25-30°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

22. MRID 485552-30 "Germicidal and Detergent Sanitizing Action of Disinfectants, Test Organism: *Aeromonas hydrophila* (ATCC 23213)," for Maguard 5%-PAA, by Jill Ruhme. Study conducted at ATS Labs. Study completion date – October 7, 2010. Project Number A09956.

This study was conducted against *Aeromonas hydrophila* (ATCC 23213). Two lots (Lots B and C) of the product, Maguard 5%-PAA, were tested using ATS Laboratory Protocol No. MC03071210.GDST.1 (copy provided). Use solutions were prepared by adding 1.00 mL of the product and 767 mL of 500 ppm AOAC synthetic hard water (titrated at 508 ppm; a 1:768 dilution). The absorbance value of the culture suspension was measured (at 620 nm) using a spectrophotometer; no further adjustment was necessary. Use solutions were not tested in the presence of a 5% organic soil load. A 99.0-mL aliquot of each use solution was transferred to duplicate 250-300 mL Erlenmeyer flasks and placed in a water bath at 25.0°C. One-mL bacterial suspension was added to each flask. One-mL aliquots of the bacterium-product mixture were transferred to 9 mL of Lethen Broth with 0.1% sodium thiosulfate and 0.01% Catalase exactly 30 seconds after the addition of the bacterial suspension. After vortex mixing, four 1.0 mL and four 0.1 mL aliquots of the neutralized use solution were plated in tryptone glucose extract agar. All plates were incubated for 44.25 hours at 35-37°C. Following incubation, the colonies were counted. Controls included those for numbers count, purity, sterility, viability, and neutralization confirmation.

Note: The laboratory reported a failed study set up on August 13, 2010. In the study, the numbers control failed to meet the acceptance criterion of $75-125 \times 10^6$ CFU/mL. The laboratory did not accept the assay. These data were not used to evaluate efficacy of the product. Testing was repeated on September 1, 2010. See page 8 and Attachment I of the laboratory report.

Note: Protocol deviations/amendments reported in the study were reviewed.

23. MRID 485552-31 "Germicidal and Detergent Sanitizing Action of Disinfectants, Test Organism: *Clostridium perfringens* (ATCC 13124)," for Maguard PAA-5%, by Anne Stemper. Study conducted at ATS Labs. Study completion date – September 16, 2010. Project Number A09971.

This study was conducted against *Clostridium perfringens* (ATCC 13124). Two lots (Lots B and C) of the product, Maguard PAA-5%, were tested using ATS Laboratory Protocol No. MC03071510.GDST.5 (copy provided). Use solutions were prepared by adding 2.00 mL of the product and 1,534 mL of 500 ppm AOAC synthetic hard water (titrated at 500 ppm; a 1:768 dilution). The culture suspension was adjusted to target a 1×10^{10} CFU/mL culture suspension. The absorbance value of the culture suspension was measured (at 620 nm) using a spectrophotometer. The absorbance value was determined to be 2.380; no further adjustment was necessary. Use solutions were not tested in the presence of a 5% organic soil load. A 99.0-mL aliquot of each use solution was transferred to duplicate 250-300 mL Erlenmeyer flasks and placed in a water bath at 25.0°C. One-mL bacterial suspension was added to each flask. One-mL aliquots of the bacterium-product mixture were transferred to 9 mL of Lethen Broth with 0.1% sodium thiosulfate and 0.01% Catalase exactly 30 seconds after the addition of the

bacterial suspension. After vortex mixing, four 1.0 mL and four 0.1 mL aliquots of the neutralized use solution were plated in tryptic soy agar with 5% sheep's blood. All plates were incubated for 48±4 hours at 35-37°C under anaerobic conditions. The plates were stored for 2 days at 2-8°C prior to reading. Following incubation and storage, the colonies were counted. Controls included those for numbers count, purity, sterility, viability, and neutralization confirmation.

24. MRID 485552-32 "Germicidal and Detergent Sanitizing Action of Disinfectants, Test Organism: *Escherichia coli* (ATCC 11229)," for Maguard 5%-PAA, by Jill Ruhme. Study conducted at ATS Labs. Study completion date – February 18, 2010. Project Number A08934.

This study was conducted against *Escherichia coli* (ATCC 11229). Three lots (Lots A, B, and C) of the product, Maguard 5%-PAA, were tested using ATS Laboratory Protocol No. MC03120109.GDST.1 (copy provided). All product lots tested were at least 60 days old at the time of testing. Use solutions were prepared by adding 1.00 mL of the product and 767 mL of 500 ppm AOAC synthetic hard water (titrated at 496 ppm; a 1:768 dilution). The inoculum was standardized using McFarland standards and phosphate buffer dilution water to target $\sim 1.0 \times 10^{10}$ CFU/mL. Use solutions were not tested in the presence of a 5% organic soil load. A 99.0-mL aliquot of each use solution was transferred to each of two 250-300 mL Erlenmeyer flasks and placed in a water bath at 19.0°C. One-mL bacterial suspension was added to each flask. One-mL aliquots of the bacterium-product mixture were transferred to 9 mL of Lethen Broth with 0.1% sodium thiosulfate and 0.05% Catalase exactly 30 seconds after the addition of the bacterial suspension. After vortex mixing, four 1.0 mL and four 0.1 mL aliquots of the neutralized use solution were plated in tryptone glucose extract agar. All plates were incubated for 49 hours and 20 minutes at 35-37°C. The plates were stored for 2 days at 2-8°C prior to reading. Following incubation and storage, the colonies were counted. Controls included those for numbers count, purity, sterility, viability, and neutralization confirmation.

Note: Protocol deviations/amendments reported in the study were reviewed.

25. MRID 485552-33 "Germicidal and Detergent Sanitizing Action of Disinfectants, Test Organism: *Escherichia coli* O157:H7 (ATCC 35150)," for Maguard 5%-PAA, by Jill Ruhme. Study conducted at ATS Labs. Study completion date – September 30, 2010. Project Number A09961.

This study was conducted against *Escherichia coli* O157:H7 (ATCC 35150). Two lots (Lots B and C) of the product, Maguard 5%-PAA, were tested using ATS Laboratory Protocol No. MC03071210.GDST.4 (copy provided). Use solutions were prepared by adding 1.00 mL of the product and 767 mL of 500 ppm AOAC synthetic hard water (titrated at 500 ppm; a 1:768 dilution). The culture suspension was adjusted to target a 1×10^{10} CFU/mL culture suspension. The absorbance value of the culture suspension was measured (at 620 nm) using a spectrophotometer; the absorbance value was determined to be 1.949. Use solutions were not tested in the presence of a 5% organic soil load. A 99.0-mL aliquot of each use solution was transferred to duplicate 250-300 mL Erlenmeyer flasks and placed in a water bath at 25.0°C. One-mL bacterial suspension was added to each flask. One-mL aliquots of the bacterium-product mixture were transferred to 9 mL of Lethen Broth with 0.1% sodium thiosulfate and 0.01% Catalase exactly 30 seconds after the addition of the bacterial suspension. After vortex mixing, four 1.0 mL and four 0.1 mL aliquots of the neutralized use solution were plated in tryptone glucose extract agar. All plates were incubated for 47 hours at 35-37°C. The plates were stored for 2 days at 2-8°C prior to reading. Following incubation and storage, the colonies

were counted. Controls included those for numbers count, purity, sterility, viability, and neutralization confirmation.

26. MRID 485552-34 "Germicidal and Detergent Sanitizing Action of Disinfectants, Test Organism: *Escherichia coli* O111:H8 (ATCC BAA-184)," for Maguard 5%-PAA, by Jill Ruhme. Study conducted at ATS Labs. Study completion date – September 21, 2010. Project Number A09958.

This study was conducted against *Escherichia coli* O111:H8 (ATCC BAA-184). Two lots (Lots B and C) of the product, Maguard 5%-PAA, were tested using ATS Laboratory Protocol No. MC03071210.GDST.2 (copy provided). Use solutions were prepared by adding 2.00 mL of the product and 1,534 mL of 500 ppm AOAC synthetic hard water (titrated at 500 ppm; a 1:768 dilution). The absorbance value of the culture suspension was measured (at 620 nm) using a spectrophotometer. The absorbance value was determined to be 2.365; no further adjustment was necessary. Use solutions were not tested in the presence of a 5% organic soil load. A 99.0-mL aliquot of each use solution was transferred to duplicate 250-300 mL Erlenmeyer flasks and placed in a water bath at 25.0°C. One-mL bacterial suspension was added to each flask. One-mL aliquots of the bacterium-product mixture were transferred to 9 mL of Lethen Broth with 0.1% sodium thiosulfate and 0.01% Catalase exactly 30 seconds after the addition of the bacterial suspension. After vortex mixing, four 1.0 mL and four 0.1 mL aliquots of the neutralized use solution were plated in tryptone glucose extract agar. All plates were incubated for 44 hours at 35-37°C. The plates were stored for 2 days at 2-8°C prior to reading. Following incubation and storage, the colonies were counted. Controls included those for numbers count, purity, sterility, viability, and neutralization confirmation.

27. MRID 485552-35 "Germicidal and Detergent Sanitizing Action of Disinfectants, Test Organism: *Enterobacter sakazakii* (ATCC 29544)," for Maguard 5%-PAA, by Becky Lien. Study conducted at ATS Labs. Study completion date – September 9, 2010. Project Number A09999.

This study was conducted against *Enterobacter sakazakii* (ATCC 29544). Two lots (Lots B and C) of the product, Maguard 5%-PAA, were tested using ATS Laboratory Protocol No. MC03071210.GDST.6 (copy provided). Use solutions were prepared by adding 2.00 mL of the product and 1,534 mL of 500 ppm AOAC synthetic hard water (titrated at 500 ppm; a 1:768 dilution). The absorbance value of the culture suspension was measured (at 620 nm) using a spectrophotometer; the absorbance value was determined to be 1.875. Use solutions were not tested in the presence of a 5% organic soil load. A 99.0-mL aliquot of each use solution was transferred to duplicate 250-300 mL Erlenmeyer flasks and placed in a water bath at 25.0°C. One-mL bacterial suspension was added to each flask. One-mL aliquots of the bacterium-product mixture were transferred to 9 mL of Lethen Broth with 0.1% sodium thiosulfate and 0.01% Catalase exactly 30 seconds after the addition of the bacterial suspension. After vortex mixing, four 1.0 mL and four 0.1 mL aliquots of the neutralized use solution were plated in tryptone glucose extract agar. All plates were incubated for 46 hours at 25-30°C. The plates were stored for 2 days at 2-8°C prior to reading. Following incubation and storage, the colonies were counted. Controls included those for numbers count, purity, sterility, viability, and neutralization confirmation.

28. MRID 485552-36 "Germicidal and Detergent Sanitizing Action of Disinfectants, Test Organism: *Klebsiella pneumoniae* (ATCC 4352)" for Maguard 5%-PAA, by Anne Stemper. Study conducted at ATS Labs. Study completion date – September 10, 2010. Project Number A09973.

This study was conducted against *Klebsiella pneumoniae* (ATCC 4352). Two lots (Lots B and C) of the product, Maguard 5%-PAA, were tested using ATS Laboratory Protocol No. MC03071210.GDST.8 (copy provided). Use solutions were prepared by adding 1.00 mL of the product and 767 mL of 500 ppm AOAC synthetic hard water (titrated at 500 ppm; a 1:768 dilution). The absorbance value of the culture suspension was measured (at 620 nm) using a spectrophotometer. The absorbance value was determined to be 2.005. Phosphate buffer dilution water was added to the culture suspension. The absorbance value was re-evaluated and determined to be 1.943. Phosphate buffer dilution water was added once more to the culture suspension. The absorbance value was re-evaluated and determined to be 1.836. No further adjustment was necessary. Use solutions were not tested in the presence of a 5% organic soil load. A 99.0-mL aliquot of each use solution was transferred to duplicate 250-300 mL Erlenmeyer flasks and placed in a water bath at 25.0°C. One-mL bacterial suspension was added to each flask. One-mL aliquots of the bacterium-product mixture were transferred to 9 mL of Lethen Broth with 0.1% sodium thiosulfate and 0.01% Catalase exactly 30 seconds after the addition of the bacterial suspension. After vortex mixing, four 1.0 mL and four 0.1 mL aliquots of the neutralized use solution were plated in tryptone glucose extract agar. All plates were incubated for 48±4 hours at 35-37°C. The plates were stored for 2 days at 2-8°C prior to reading. Following incubation and storage, the colonies were counted. Controls included those for numbers count, purity, sterility, viability, and neutralization confirmation.

Note: Protocol deviations/amendments reported in the study were reviewed.

29. MRID 485552-37 "Germicidal and Detergent Sanitizing Action of Disinfectants, Test Organism: *Shigella dysenteriae* (ATCC 11835)" for Maguard 5%-PAA, by Anne Stemper. Study conducted at ATS Labs. Study completion date – September 13, 2010. Project Number A10001.

This study was conducted against *Shigella dysenteriae* (ATCC 11835). Two lots (Lots B and C) of the product, Maguard 5%-PAA, were tested using ATS Laboratory Protocol No. MC03071210.GDST.12 (copy provided). Use solutions were prepared by adding 2.00 mL of the product and 1,534 mL of 500 ppm AOAC synthetic hard water (titrated at 500 ppm; a 1:768 dilution). The absorbance value of the culture suspension was measured (at 620 nm) using a spectrophotometer. The absorbance value was determined to be 2.088; no further adjustment was necessary. Use solutions were not tested in the presence of a 5% organic soil load. A 99.0-mL aliquot of each use solution was transferred to duplicate 250-300 mL Erlenmeyer flasks and placed in a water bath at 25.0°C. One-mL bacterial suspension was added to each flask. One-mL aliquots of the bacterium-product mixture were transferred to 9 mL of Lethen Broth with 0.1% sodium thiosulfate and 0.01% Catalase exactly 30 seconds after the addition of the bacterial suspension. After vortex mixing, four 1.0 mL and four 0.1 mL aliquots of the neutralized use solution were plated in tryptic soy agar with 5% sheep's blood. All plates were incubated for 48±4 hours at 35-37°C. The plates were stored for 2 days at 2-8°C prior to reading. Following incubation and storage, the colonies were counted. Controls included those for numbers count, purity, sterility, viability, and neutralization confirmation.

30. MRID 485552-38 "Germicidal and Detergent Sanitizing Action of Disinfectants, Test Organism: *Salmonella enterica* (ATCC 10708)" for Maguard 5%-PAA, by Becky Lien. Study conducted at ATS Labs. Study completion date – September 8, 2010. Project Number A10000.

This study was conducted against *Salmonella enterica* (ATCC 10708). Two lots (Lots B and C) of the product, Maguard 5%-PAA, were tested using ATS Laboratory Protocol No. MC03071210.GDST.9 (copy provided). Use solutions were prepared by adding 2.00 mL of the product and 1,534 mL of 500 ppm AOAC synthetic hard water (titrated at 500 ppm; a 1:768 dilution). The absorbance value of the culture suspension was measured (at 620 nm) using a spectrophotometer. The absorbance value was determined to be 1.838. Use solutions were not tested in the presence of a 5% organic soil load. A 99.0-mL aliquot of each use solution was transferred to duplicate 250-300 mL Erlenmeyer flasks and placed in a water bath at 25.0°C. One-mL bacterial suspension was added to each flask. One-mL aliquots of the bacterium-product mixture were transferred to 9 mL of Lethen Broth with 0.1% sodium thiosulfate and 0.01% Catalase exactly 30 seconds after the addition of the bacterial suspension. After vortex mixing, four 1.0 mL and four 0.100 mL aliquots of the neutralized use solution were plated in tryptone glucose extract agar. All plates were incubated for 46 hours at 35-37°C. The plates were stored for 2 days at 2-8°C prior to reading. Following incubation and storage, the colonies were counted. Controls included those for numbers count, purity, sterility, viability, and neutralization confirmation.

31. MRID 485552-39 "Germicidal and Detergent Sanitizing Action of Disinfectants, Test Organism: *Shigella sonnei* (ATCC 25931)" for Maguard PAA-5%, by Anne Stemper. Study conducted at ATS Labs. Study completion date – September 7, 2010. Project Number A09953.

This study was conducted against *Shigella sonnei* (ATCC 25931). Two lots (Lots B and C) of the product, Maguard PAA-5%, were tested using ATS Laboratory Protocol No. MC03071510.GDST.4 (copy provided). Use solutions were prepared by adding 1.00 mL of the product and 767 mL of 500 ppm AOAC synthetic hard water (titrated at 504 ppm; a 1:768 dilution). The absorbance value of the culture suspension was measured (at 620 nm) using a spectrophotometer. The absorbance value was determined to be 2.352; no further adjustment was necessary. Use solutions were not tested in the presence of a 5% organic soil load. A 99.0-mL aliquot of each use solution was transferred to duplicate 250-300 mL Erlenmeyer flasks and placed in a water bath at 25.0°C. One-mL bacterial suspension was added to each flask. One-mL aliquots of the bacterium-product mixture were transferred to 9 mL of Lethen Broth with 0.1% sodium thiosulfate and 0.01% Catalase exactly 30 seconds after the addition of the bacterial suspension. After vortex mixing, four 1.0 mL and four 0.1 mL aliquots of the neutralized use solution were plated in tryptone glucose extract agar. All plates were incubated for 48±4 hours at 35-37°C. Following incubation, the colonies were counted. Controls included those for numbers count, purity, sterility, viability, and neutralization confirmation.

32. MRID 485552-40 "Germicidal and Detergent Sanitizing Action of Disinfectants, Test Organism: *Salmonella typhi* (ATCC 6539)," for Maguard 5%-PAA, by Jill Ruhme. Study conducted at ATS Labs. Study completion date – September 27, 2010. Project Number A09963.

This study was conducted against *Salmonella typhi* (ATCC 6539). Two lots (Lots B and C) of the product, Maguard 5%-PAA, were tested using ATS Laboratory Protocol No. MC03071210.GDST.11 (copy provided). Use solutions were prepared by adding 1.00 mL of the product and 767 mL of 500 ppm AOAC synthetic hard water (titrated at 500 ppm; a 1:768 dilution). The absorbance value of the culture suspension was measured (at 620 nm) using a spectrophotometer. The absorbance value was determined to be 1.964. Use solutions were not tested in the presence of a 5% organic soil load. A 99.0-mL aliquot of each use solution was transferred to duplicate 250-300 mL Erlenmeyer flasks and placed in a water bath at 25.0°C.

One-mL bacterial suspension was added to each flask. One-mL aliquots of the bacterium-product mixture were transferred to 9 mL of Letheen Broth with 0.1% sodium thiosulfate and 0.01% Catalase exactly 30 seconds after the addition of the bacterial suspension. After vortex mixing, four 1.0 mL and four 0.1 mL aliquots of the neutralized use solution were plated in tryptone glucose extract agar. All plates were incubated for 44.75 hours at 35-37°C. The plates were stored for 2 days at 2-8°C prior to reading. Following incubation and storage, the colonies were counted. Controls included those for numbers count, purity, sterility, viability, and neutralization confirmation.

33. MRID 485552-41 "Germicidal and Detergent Sanitizing Action of Disinfectants, Test Organism: *Staphylococcus aureus* (ATCC 6538)" for Maguard PAA-5%, by Joshua Luedtke. Study conducted at ATS Labs. Study completion date – August 25, 2010. Project Number A09957.

This study was conducted against *Staphylococcus aureus* (ATCC 6538). One lot (Lot A) of the product, Maguard PAA-5%, was tested using ATS Laboratory Protocol No. MC03071510.GDST (copy provided). The product lot tested (i.e., Lot A) was at least 60 days old at the time of testing. A use solution was prepared by adding 1.00 mL of the product and 383 mL of 500 ppm AOAC synthetic hard water (titrated at 500 ppm; a 1:384 dilution). The absorbance value of the culture suspension was measured (at 620 nm) using a spectrophotometer. The absorbance value was determined to be 2.469; no further adjustment was necessary. The use solution was not tested in the presence of a 5% organic soil load. A 99.0-mL aliquot of the use solution was transferred to duplicate 250-300 mL Erlenmeyer flasks and placed in a water bath at 25.0°C. One-mL bacterial suspension was added to each flask. One-mL aliquots of the bacterium-product mixture were transferred to 9 mL of Letheen Broth with 0.1% sodium thiosulfate and 0.01% Catalase exactly 30 seconds after the addition of the bacterial suspension. After vortex mixing, four 1.0 mL and four 0.1 mL aliquots of the neutralized use solution were plated in tryptone glucose extract agar. All plates were incubated for 48±4 hours at 35-37°C. Following incubation, the colonies were counted. Controls included those for numbers count, purity, sterility, viability, and neutralization confirmation.

34. MRID 485552-42 "Germicidal and Detergent Sanitizing Action of Disinfectants, Test Organism: *Staphylococcus aureus* (ATCC 6538)," for Maguard PAA-5%, by Joshua Luedtke. Study conducted at ATS Labs. Study completion date – August 25, 2010. Project Number A09959.

This study was conducted against *Staphylococcus aureus* (ATCC 6538). One lot (Lot B) of the product, Maguard PAA-5%, was tested using ATS Laboratory Protocol No. MC03071510.GDST.2 (copy provided). The product lot tested (i.e., Lot B) was at least 60 days old at the time of testing. A use solution was prepared by adding 1.00 mL of the product and 383 mL of 500 ppm AOAC synthetic hard water (titrated at 500 ppm; a 1:384 dilution). The absorbance value of the culture suspension was measured (at 620 nm) using a spectrophotometer. The absorbance value was determined to be 2.469; no further adjustment was necessary. The use solution was not tested in the presence of a 5% organic soil load. A 99.0-mL aliquot of the use solution was transferred to duplicate 250-300 mL Erlenmeyer flasks and placed in a water bath at 25.0°C. One-mL bacterial suspension was added to each flask. One-mL aliquots of the bacterium-product mixture were transferred to 9 mL of Letheen Broth with 0.1% sodium thiosulfate and 0.01% Catalase exactly 30 seconds after the addition of the bacterial suspension. After vortex mixing, four 1.0 mL and four 0.1 mL aliquots of the neutralized use solution were plated in tryptone glucose extract agar. All plates were incubated for 48±4

hours at 35-37°C. Following incubation, the colonies were counted. Controls included those for numbers count, purity, sterility, viability, and neutralization confirmation.

35. MRID 485552-43 "Germicidal and Detergent Sanitizing Action of Disinfectants, Test Organism: *Staphylococcus aureus* (ATCC 6538)," for Maguard PAA-5%, by Joshua Luedtke. Study conducted at ATS Labs. Study completion date – August 25, 2010. Project Number A09960.

This study was conducted against *Staphylococcus aureus* (ATCC 6538). One lot (Lot C) of the product, Maguard PAA-5%, was tested using ATS Laboratory Protocol No. MC03071510.GDST.3 (copy provided). The product lot tested (i.e., Lot C) was at least 60 days old at the time of testing. A use solution was prepared by adding 1.00 mL of the product and 383 mL of 500 ppm AOAC synthetic hard water (titrated at 500 ppm; a 1:384 dilution). The absorbance value of the culture suspension was measured (at 620 nm) using a spectrophotometer. The absorbance value was determined to be 2.469; no further adjustment was necessary. The use solution was not tested in the presence of a 5% organic soil load. A 99.0-mL aliquot of the use solution was transferred to duplicate 250-300 mL Erlenmeyer flasks and placed in a water bath at 25.0°C. One-mL bacterial suspension was added to each flask. One-mL aliquots of the bacterium-product mixture were transferred to 9 mL of Letheen Broth with 0.1% sodium thiosulfate and 0.01% Catalase exactly 30 seconds after the addition of the bacterial suspension. After vortex mixing, four 1.0 mL and four 0.1 mL aliquots of the neutralized use solution were plated in tryptone glucose extract agar. All plates were incubated for 48±4 hours at 35-37°C. Following incubation, the colonies were counted. Controls included those for numbers count, purity, sterility, viability, and neutralization confirmation.

36. MRID 485552-44 "Germicidal and Detergent Sanitizing Action of Disinfectants, Test Organism: *Yersinia enterocolitica* (ATCC 23715)," for Maguard 5%-PAA, by Anne Stemper. Study conducted at ATS Labs. Study completion date – September 13, 2010. Project Number A09988.

This study was conducted against *Yersinia enterocolitica* (ATCC 23715). Two lots (Lots B and C) of the product, Maguard 5%-PAA, were tested using ATS Laboratory Protocol No. MC03071210.GDST.3 (copy provided). Use solutions were prepared by adding 2.00 mL of the product and 1,534 mL of 500 ppm AOAC synthetic hard water (titrated at 500 ppm; a 1:768 dilution). The absorbance value of the culture suspension was measured (at 620 nm) using a spectrophotometer. The absorbance value was determined to be 2.766. Phosphate buffer dilution water was added to the culture suspension. The absorbance value was re-evaluated and determined to be 2.602. Phosphate buffer dilution water was added once more to the culture suspension. The absorbance value was re-evaluated and determined to be 2.356. No further adjustment was necessary. Use solutions were not tested in the presence of a 5% organic soil load. A 99.0-mL aliquot of each use solution was transferred to duplicate 250-300 mL Erlenmeyer flasks and placed in a water bath at 25.0°C. One-mL bacterial suspension was added to each flask. One-mL aliquots of the bacterium-product mixture were transferred to 9 mL of Letheen Broth with 0.1% sodium thiosulfate and 0.01% Catalase exactly 30 seconds after the addition of the bacterial suspension. After vortex mixing, four 1.0 mL and four 0.1 mL aliquots of the neutralized use solution were plated in tryptic soy agar with 5% sheep's blood. All plates were incubated for 48±4 hours at 35-37°C. The plates were stored for 1 day at 2-8°C prior to reading. Following incubation and storage, the colonies were counted. Controls included those for numbers count, purity, sterility, viability, and neutralization confirmation.

37. MRID 485552-45 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Avian Adenovirus" for Maguard PAA-5%, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – July 27, 2010. Project Number A09737.

This study was conducted against Avian adenovirus (Strain Fontes; ATCC VR-280), using CEF cells (chicken embryo fibroblast cells; obtained from Charles River Laboratories; maintained in-house) as the host system. Two lots (Lots B and C) of the product, Maguard PAA-5%, were tested according to ATS Labs Protocol No. MC03051910.AADV (copy provided). Use solutions were prepared by adding 1.00 mL of the product and 426.0 mL of 400 ppm AOAC synthetic hard water (titrated at 400 ppm; a 1:427 dilution). The stock virus culture contained 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 50% relative humidity. For each lot of product, separate dried virus films were exposed to 2.00 mL of the use solution for 10 minutes at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium with 5% (v/v) heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, 2.5 µg/mL amphotericin B, 5% tryptose phosphate broth, and 2.0 mM L-glutamine. CEF cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO₂. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

38. MRID 485552-46 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Avian Influenza A (H5N1) virus" for Maguard PAA-5%, by Shanen Conway. Study conducted at ATS Labs. Study completion date – July 28, 2010. Project Number A09730.

This study was conducted against Avian influenza A (H5N1) virus (Strain VNH5N1-PR8/CDC-RG CDC #2006719965), using RMK cells (Rhesus monkey kidney cells; obtained from ViroMed Laboratories, Inc., Cell Culture Division; maintained in-house) as the host system. Two lots (Lots B and C) of the product, Maguard PAA-5%, were tested according to ATS Labs Protocol No. MC03051910.AFLU (copy provided). Use solutions were prepared by adding 1.00 mL of the product and 426.0 mL of 400 ppm AOAC synthetic hard water (titrated at 396 ppm; a 1:427 dilution). The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 22.0°C at 47.9% relative humidity. For each lot of product, separate dried virus films were exposed to 2.00 mL of the use solution for 10 minutes at 22.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium with 1% (v/v) heat-inactivated fetal bovine serum, 100 units/mL penicillin, 10 µg/mL gentamicin, and 2.5 µg/mL amphotericin B. RMK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO₂. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for input virus count, dried virus count,

cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

39. MRID 485552-47 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Avian Infectious Bronchitis virus" for Maguard PAA-5%, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – July 28, 2010. Project Number A09614.

This study was conducted against Avian infectious bronchitis virus (Strain Beaudette IB42; obtained from Solvay Animal Health), using fertilized, embryonated chicken eggs (obtained from Charles Rivers) as the host system. Two lots (Lots B and C) of the product, Maguard PAA-5%, were tested according to ATS Labs Protocol No. MC03051910.IBV (copy provided). Use solutions were prepared by adding 1.00 mL of the product and 426.0 mL of 400 ppm AOAC synthetic hard water (titrated at 392 ppm; a 1:427 dilution). The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 50% relative humidity. For each lot of product, separate dried virus films were exposed to 2.00 mL of the use solution for 10 minutes at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in sterile phosphate buffer. Ten-day old fertilized, embryonated chicken eggs were inoculated intra-allantoically in quadruplicate with 0.1 mL of the dilutions. The eggs were incubated for up to 4 days at 34-38°C at 40-80% relative humidity. The eggs were candled daily to determine the viability of the embryo. The presence of the test virus was determined by death of the embryo. Embryos viable following incubation were considered negative for the test virus. Controls included those for input virus count, dried virus count, toxicity, and neutralization. Viral and toxicity titers were calculated by the method of Spearman Karber.

Note: Protocol deviations/amendments reported in the study were reviewed.

40. MRID 485552-48 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Infectious Bursal disease" for Maguard PAA-5%, by Shanen Conway. Study conducted at ATS Labs. Study completion date – July 19, 2010. Project Number A09689.

This study was conducted against Infectious bursal disease (obtained from Solvay Animal Health), using Vero cells (ATCC CCL-81; propagated in-house) as the host system. Two lots (Lots B and C) of the product, Maguard PAA-5%, were tested according to ATS Labs Protocol No. MC03051910.IBD (copy provided). Use solutions were prepared by adding 1.00 mL of the product and 426.0 mL of 400 ppm AOAC synthetic hard water (titrated at 400 ppm; a 1:427 dilution). The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 50% relative humidity. For each lot of product, separate dried virus films were exposed to 2.00 mL of the use solution for 10 minutes at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium with 2% (v/v) heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. Vero cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were

incubated at 36-38°C in a humidified atmosphere of 5-7% CO₂. The cultures were scored periodically for 9 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

41. MRID 485552-49 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Human Coronavirus" for Maguard PAA-5%, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – July 20, 2010. Project Number A09688.

This study was conducted against Human coronavirus (Strain 229E; ATCC VR-740), using WI-38 cells (human embryonic lung fibroblasts; ATCC CCL-75; propagated in-house) as the host system. Two lots (Lots B and C) of the product, Maguard PAA-5%, were tested according to ATS Labs Protocol No. MC03051910.COR (copy provided). Use solutions were prepared by adding 1.00 mL of the product and 426.0 mL of 400 ppm AOAC synthetic hard water (titrated at 396 ppm; a 1:427 dilution). The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 54% relative humidity. For each lot of product, separate dried virus films were exposed to 2.00 mL of the use solution for 10 minutes at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium with 2% (v/v) heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. WI-38 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 31-35°C in a humidified atmosphere of 5-7% CO₂. The cultures were scored periodically for 10 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

Note: Protocol deviations/amendments reported in the study were reviewed.

42. MRID 485552-50 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Utilizing Duck Hepatitis B Virus as a Surrogate Virus for Human Hepatitis B Virus" for Maguard PAA-5%, by Kelleen Gutzmann. Study conducted at ATS Labs. Study completion date – September 13, 2010. Project Number A09955.

This study, under the direction of Study Director Kelleen Gutzmann, was conducted against Duck hepatitis B virus (Strain 7/31/07; obtained from HepadnaVirus Testing, Inc., Palo Alto, CA), using primary duck hepatocytes (cultures prepared by Valley Research Institute personnel using hatchling ducks received from Metzger Farms) as the host system. Two lots (Lots B and C) of the product, Maguard PAA-5%, were tested according to ATS Labs Protocol No. MC03051910.DHBV.2 (copy provided). Use solutions were prepared by adding 1.00 mL of the product and 426 mL of 400 ppm AOAC synthetic hard water (titrated at 404 ppm; a 1:427 dilution). The stock virus culture contained 100% duck serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 30 minutes at 20.0°C at 40% relative humidity. Two replicates per product lot were tested. For each lot of product,

separate dried virus films were exposed to 2.00 mL of the use solution for 10 minutes at 20.0°C. Following exposure, each plate was scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Leibovitz L-15 medium with 0.1% glucose, 10 µM dexamethasone, 10 µg/mL insulin, 20 mM HEPES, 10 µg/mL gentamicin, and 100 units/mL penicillin. Primary duck hepatocytes in multi-well culture dishes were inoculated in quadruplicate with 1.00 mL of the dilutions. Test medium was added to sufficiently cover the monolayer during the adsorption period. The cultures were incubated overnight at 36-38°C in a humidified atmosphere of 5-7% CO₂ for viral adsorption. Post-adsorption, the cultures were re-fed. The cultures were returned to incubation for a total of 9 days at 36-38°C in a humidified atmosphere of 5-7% CO₂. The cultures were re-fed, as necessary. On the final day of incubation, the cultures were scored microscopically for cytotoxicity. An indirect immunofluorescence assay was then performed. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

43. MRID 485552-51 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Utilizing Duck Hepatitis B Virus as a Surrogate Virus for Human Hepatitis B Virus – Confirmatory Assay" for Maguard PAA-5%, by Shanen Conway. Study conducted at ATS Labs. Study completion date – September 10, 2010. Project Number A09954.

This confirmatory study, under the direction of Study Director Shanen Conway, was conducted against Duck hepatitis B virus (Strain 7/31/07; obtained from HepadnaVirus Testing, Inc., Palo Alto, CA), using primary duck hepatocytes (cultures prepared by Valley Research Institute personnel using hatchling ducks received from Metzger Farms) as the host system. One lot (Lot B) of the product, Maguard PAA-5%, was tested according to ATS Labs Protocol No. MC03051910.DHBV.1 (copy provided). A use solution was prepared by adding 1.00 mL of the product and 426 mL of 400 ppm AOAC synthetic hard water (titrated at 400 ppm; a 1:427 dilution). The stock virus culture contained 100% duck serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 30 minutes at 20.0°C at 40% relative humidity. Two replicates of the single product lot were tested. For the single product lot, separate dried virus films were exposed to 2.00 mL of the use solution for 10 minutes at 20.0°C. Following exposure, each plate was scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Leibovitz L-15 medium with 0.1% glucose, 10 µM dexamethasone, 10 µg/mL insulin, 20 mM HEPES, 10 µg/mL gentamicin, and 100 units/mL penicillin. Primary duck hepatocytes in multi-well culture dishes were inoculated in quadruplicate with 1.0 mL of the dilutions. Test medium was added to each culture well prior to inoculation. The cultures were incubated overnight at 36-38°C in a humidified atmosphere of 5-7% CO₂ for viral adsorption. Post-adsorption, the cultures were re-fed. The cultures were returned to incubation for a total of 9 days at 36-38°C in a humidified atmosphere of 5-7% CO₂. The cultures were re-fed, as necessary. On the final day of incubation, the cultures were scored microscopically for cytotoxicity. An indirect immunofluorescence assay was then performed. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

44. MRID 485552-52 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Herpes simplex virus type 1" for Maguard PAA-5%, by Shanen Conway. Study conducted at ATS Labs. Study completion date – July 19, 2010. Project Number A09721.

This study was conducted against Herpes simplex virus type 1 (Strain F(1); ATCC VR-733), using rabbit kidney cells (RK cells; obtained from ViroMed Laboratories, Inc., Cell Culture Division; maintained in-house) as the host system. Two lots (Lots B and C) of the product, Maguard PAA-5%, were tested according to ATS Labs Protocol No. MC03051910.HSV1 (copy provided). Use solutions were prepared by adding 1.00 mL of the product and 426.0 mL of 400 ppm AOAC synthetic hard water (titrated at 396 ppm; a 1:427 dilution). The stock virus culture contained 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 50% relative humidity. For each lot of product, separate dried virus films were exposed to 2.00 mL of the use solution for 10 minutes at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium with 5% (v/v) heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. RK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO₂. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

45. MRID 485552-53 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Herpes simplex virus type 2" for Maguard PAA-5%, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – July 20, 2010. Project Number A09722.

This study was conducted against Herpes simplex virus type 2 (Strain G; ATCC VR-734), using rabbit kidney cells (RK cells; obtained from ViroMed Laboratories, Inc., Cell Culture Division; maintained in-house) as the host system. Two lots (Lots B and C) of the product, Maguard PAA-5%, were tested according to ATS Labs Protocol No. MC03051910.HSV2 (copy provided). Use solutions were prepared by adding 1.00 mL of the product and 426.0 mL of 400 ppm AOAC synthetic hard water (titrated at 396 ppm; a 1:427 dilution). The stock virus culture contained 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 50% relative humidity. For each lot of product, separate dried virus films were exposed to 2.00 mL of the use solution for 10 minutes at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium with 5% (v/v) heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. RK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO₂. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

46. MRID 485552-54 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Human Immunodeficiency virus type 1" for

Maguard PAA-5%, by Shanen Conway. Study conducted at ATS Labs. Study completion date – July 30, 2010. Project Number A09739.

This study was conducted against Human immunodeficiency virus type 1 (Strain HTLV-III_B; obtained from Advanced Biotechnologies, Inc., Columbia, MD), using MT-2 cells (human T-cell leukemia cells; obtained through the AIDS Research and Reference Reagent Program, Division of AIDS, NIAID, NIH from Dr. Douglas Richman; maintained in-house) as the host system. Two lots (Lots B and C) of the product, Maguard PAA-5%, were tested according to ATS Labs Protocol No. MC03051910.HIV (copy provided). Use solutions were prepared by adding 1.00 mL of the product and 426.0 mL of 400 ppm AOAC synthetic hard water (titrated at 396 ppm; a 1:427 dilution). The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 23.0°C. For each lot of product, separate dried virus films were exposed to 2.00 mL of the use solution for 10 minutes at 21.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in RPMI-1640 with 10% (v/v) heat-inactivated fetal bovine serum, 2.0 mM L-glutamine, and 50 µg/mL gentamicin. MT-2 cells in multi-well culture dishes were inoculated in quadruplicate with 0.2 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO₂. The cultures were scored periodically for 9 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

47. MRID 485552-55 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Infectious Laryngotracheitis" for Maguard PAA-5%, by Shanen Conway. Study conducted at ATS Labs. Study completion date – July 23, 2010. Project Number A09736.

This study was conducted against Infectious laryngotracheitis (Strain LT-IVAX; obtained from the Poultry Health and Specialties, St. Cloud, MN), using CEL cells (chicken embryo liver cells; obtained from Charles River Laboratories; propagated in-house) as the host system. Two lots (Lots B and C) of the product, Maguard PAA-5%, were tested according to ATS Labs Protocol No. MC03051910.ILGT (copy provided). Use solutions were prepared by adding 1.00 mL of the product and 426.0 mL of 400 ppm AOAC synthetic hard water (titrated at 400 ppm; a 1:427 dilution). The stock virus culture contained 5% lamb serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 50% relative humidity. For each lot of product, separate dried virus films were exposed to 2.00 mL of the use solution for 10 minutes at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium with 5% (v/v) heat-inactivated lamb serum, 5% (v/v) tryptose phosphate broth, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. CEL cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO₂. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

Note: Protocol deviations/amendments reported in the study were reviewed.

48. MRID 485552-56 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Newcastle disease virus" for Maguard PAA-5%, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – July 27, 2010. Project Number A09590.

This study was conducted against Newcastle disease virus (Strain B1, Hitchner, or Blacksburg; ATCC VR-108), using CEF cells (chicken embryo fibroblast cells; obtained from Charles River; maintained in-house) as the host system. Two lots (Lots B and C) of the product, Maguard PAA-5%, were tested according to ATS Labs Protocol No. MC03051910.NEW (copy provided). Use solutions were prepared by adding 1.00 mL of the product and 426.0 mL of 400 ppm AOAC synthetic hard water (titrated at 400 ppm; a 1:427 dilution). The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 50% relative humidity. For each lot of product, separate dried virus films were exposed to 2.00 mL of the use solution for 10 minutes at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium with 2% (v/v) heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, 2.5 µg/mL amphotericin B, 5% tryptose phosphate broth, and 2.0 mM L-glutamine. CEF cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO₂. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

49. MRID 485552-57 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Porcine Rotavirus" for Maguard PAA-5%, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – June 24, 2010. Project Number A09592.

This study was conducted against Porcine rotavirus (Strain OSU (attenuated); ATCC VR-893), using MA-104 cells (Rhesus monkey kidney cells; obtained from Diagnostics Hybrids, Inc., Athens, OH; propagated in-house) as the host system. Two lots (Lots B and C) of the product, Maguard PAA-5%, were tested according to ATS Labs Protocol No. MC03051910.PROT (copy provided). Use solutions were prepared by adding 1.00 mL of the product and 426.0 mL of 400 ppm AOAC synthetic hard water (titrated at 398 ppm; a 1:427 dilution). The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 50% relative humidity. For each lot of product, separate dried virus films were exposed to 2.00 mL of the use solution for 10 minutes at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in serum-free Minimum Essential Medium with 0.5 µg/mL trypsin, 2.0 mM L-glutamine, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. MA-104 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The inoculum was

allowed to adsorb for 60 minutes at 36-38°C in a humidified atmosphere of 5-7% CO₂. Post-adsorption, the cultures were re-fed. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO₂. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

50. MRID 485552-58 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Porcine Respiratory & Reproductive Syndrome virus" for Maguard PAA-5%, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – June 24, 2010. Project Number A09591.

This study was conducted against Porcine Respiratory & Reproductive Syndrome virus (Strain NVSL; obtained from the University of Kentucky), using MARC-145 cells (obtained from National Veterinary Services Laboratories, Ames, IA; propagated in-house) as the host system. Two lots (Lots B and C) of the product, Maguard PAA-5%, were tested according to ATS Labs Protocol No. MC03051910.PRRS (copy provided). Use solutions were prepared by adding 1.00 mL of the product and 426.0 mL of 400 ppm AOAC synthetic hard water (titrated at 398 ppm; a 1:427 dilution). The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 50% relative humidity. For each lot of product, separate dried virus films were exposed to 2.00 mL of the use solution for 10 minutes at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium with 5% (v/v) heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. MARC-145 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO₂. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

51. MRID 485552-59 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Pseudorabies" for Maguard PAA-5%, by Shanen Conway. Study conducted at ATS Labs. Study completion date – July 13, 2010. Project Number A09593.

This study was conducted against Pseudorabies (Strain Aujeszky; ATCC VR-135), using CRFK cells (feline kidney cells; ATCC CCL-94; propagated in-house) as the host system. Two lots (Lots B and C) of the product, Maguard PAA-5%, were tested according to ATS Labs Protocol No. MC03051910.PSRV (copy provided). Use solutions were prepared by adding 1.00 mL of the product and 426.0 mL of 400 ppm AOAC synthetic hard water (titrated at 400 ppm; a 1:427 dilution). The stock virus culture contained 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 50% relative humidity. For each lot of product, separate dried virus films were exposed to 2.00 mL of the use solution for 10 minutes at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential

Medium with 5% (v/v) heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. CRFK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO₂. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

52. MRID 485552-60 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Transmissible gastroenteritis" for Maguard PAA-5%, by Shanen Conway. Study conducted at ATS Labs. Study completion date – August 24, 2010. Project Number A09662.

This study was conducted against Transmissible gastroenteritis (strain not specified; obtained from the University of Minnesota), using ST cells (porcine fetal testis cells; obtained from ViroMed Laboratories, Inc., Cell Culture Division; maintained in-house) as the host system. Two lots (Lots B and C) of the product, Maguard PAA-5%, were tested according to ATS Labs Protocol No. MC03051910.TGE (copy provided). Use solutions were prepared by adding 1.00 mL of the product and 426.0 mL of 400 ppm AOAC synthetic hard water (titrated at 400 ppm; a 1:427 dilution). The stock virus culture contained 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 50% relative humidity. For each lot of product, separate dried virus films were exposed to 2.00 mL of the use solution for 10 minutes at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium with 5% (v/v) heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. ST cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO₂. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

Note: The laboratory reported a failed study set up on July 2, 2010. In the study, virus was present in the lowest dilution of both product lots tested. Testing was repeated on August 3, 2010 to evaluate for potential false positive results. See page 8 and Attachment I of the laboratory report.

Note: Protocol deviations/amendments reported in the study were reviewed.

53. MRID 485552-61 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Vesicular Stomatitis" for Maguard PAA-5%, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – July 20, 2010. Project Number A09569.

This study was conducted against Vesicular stomatitis (Strain Indiana; ATCC VR-158), using LLC-MK₂ cells (obtained from ViroMed Laboratories, Inc., Cell Culture Division; maintained in-house) as the host system. Two lots (Lots B and C) of the product, Maguard PAA-5%, were tested according to ATS Labs Protocol No. MC03051910.VSTV (copy provided). Use solutions were prepared by adding 1.00 mL of the product and 426.0 mL of 400 ppm AOAC

synthetic hard water (titrated at 392 ppm; a 1:427 dilution). The stock virus culture contained 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 50% relative humidity. For each lot of product, separate dried virus films were exposed to 2.00 mL of the use solution for 10 minutes at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium with 5% heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5µg/mL amphotericin B. LLC-MK₂ cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO₂. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

V. RESULTS

MRID Number	Organism	No. Exhibiting Growth/ Total No. Tested			Carrier Population (CFU/ carrier)
		Lot A	Lot B	Lot C	
10-Minute Exposure Time at a 1:427 Dilution					
485552-09	<i>Staphylococcus aureus</i>	0/60	---	---	9.5 x 10 ⁶
485552-10	<i>Staphylococcus aureus</i>	---	0/60	---	6.9 x 10 ⁶
485552-11	<i>Staphylococcus aureus</i>	---	---	1/60	1.49 x 10 ⁷
485552-12	<i>Salmonella enterica</i>	0/60	---	---	1.61 x 10 ⁶
485552-13	<i>Salmonella enterica</i>	---	0/60	---	5.2 x 10 ⁶
485552-14	<i>Salmonella enterica</i>	---	---	1/60	1.02 x 10 ⁶
485552-18	Vancomycin Resistant <i>Enterococcus faecalis</i>	---	0/10	0/10	5.4 x 10 ⁶
485552-19	Vancomycin Intermediate Resistant	---	0/10	0/10	2.19 x 10 ⁵
	<i>Staphylococcus aureus</i>				
485552-21	<i>Bordetella bronchiseptica</i>	---	0/10	0/10	1.86 x 10 ⁷
485552-22	<i>Corynebacterium ammoniaenes</i>	---	1°=0/10 2°=0/10	1°=0/10 2°=0/10	7.6 x 10 ⁵
485552-25	<i>Listeria monocytogenes</i>	---	0/10	0/10	1.27 x 10 ⁵
485552-26	<i>Shigella sonnei</i>	---	0/10	0/10	5.1 x 10 ⁶
485552-27	<i>Salmonella typhi</i>	---	0/10	0/10	5.5 x 10 ⁴
485552-28	<i>Escherichia coli</i> O157:H7	---	0/10	0/10	1.49 x 10 ⁶
485552-29	<i>Trichophyton mentagrophytes</i>	---	1°=0/10 2°=0/10	1°=0/10 2°=0/10	1.58 x 10 ⁵
10-Minute Exposure Time at a 1:320 Dilution					
485552-15	<i>Pseudomonas aeruginosa</i>	1/60	---	---	3.3 x 10 ⁷
485552-16	<i>Pseudomonas aeruginosa</i>	---	0/60	---	7.9 x 10 ⁶
485552-17	<i>Pseudomonas aeruginosa</i>	---	---	1/60	6.1 x 10 ⁶

MRID Number	Organism	No. Exhibiting Growth/ Total No. Tested			Carrier Population (CFU/ carrier)
		Lot A	Lot B	Lot C	
485552-20	Community Acquired Methicillin Resistant <i>Staphylococcus aureus</i>	---	0/10	0/10	3.3×10^6
485552-23	<i>Campylobacter jejuni</i>	---	0/10	0/10	3.40×10^8
485552-24	<i>Klebsiella pneumoniae</i>	---	0/10	0/10	5.8×10^5

MRID Number	Organism	Results			Dried Virus Count
			Lot No. B	Lot No. C	
10-Minute Exposure Time at a 1:427 Dilution					
485552-45	Avian adenovirus	10 ⁻¹ to 10 ⁻⁸ dilutions	Complete inactivation	Complete inactivation	10 ^{4.5}
		TCID ₅₀ /0.1 mL	≤10 ^{0.5}	≤10 ^{0.5}	TCID ₅₀ /0.1 mL
485552-46	Avian influenza A (H5N1) virus	10 ⁻¹ to 10 ⁻⁷ dilutions	Complete inactivation	Complete inactivation	10 ^{5.5}
		TCID ₅₀ /0.1 mL	≤10 ^{0.5}	≤10 ^{0.5}	TCID ₅₀ /0.1 mL
485552-47	Avian infectious bronchitis virus	10 ⁻¹ to 10 ⁻⁶ dilutions	Complete inactivation	Complete inactivation	10 ^{5.17}
		LD ₅₀ /0.1 mL	≤10 ^{0.5}	≤10 ^{0.5}	LD ₅₀ /0.1 mL
485552-48	Infectious bursal disease	10 ⁻¹ to 10 ⁻⁸ dilutions	Complete inactivation	Complete inactivation	10 ^{5.0}
		TCID ₅₀ /0.1 mL	≤10 ^{0.5}	≤10 ^{0.5}	TCID ₅₀ /0.1 mL
485552-49	Human coronavirus	10 ⁻¹ to 10 ⁻⁶ dilutions	Complete inactivation	Complete inactivation	10 ^{5.5}
		TCID ₅₀ /0.1 mL	≤10 ^{0.5}	≤10 ^{0.5}	TCID ₅₀ /0.1 mL
485552-50	Duck hepatitis B virus	10 ⁻² to 10 ⁻⁴ dilutions	Complete inactivation	Complete inactivation	10 ^{5.5}
		TCID ₅₀ /1.0 mL	≤10 ^{1.5}	≤10 ^{1.5}	TCID ₅₀ /1.0 mL
485552-51	Duck hepatitis B virus	10 ⁻² to 10 ⁻⁴ dilutions	Complete inactivation	---	10 ^{5.5}
		TCID ₅₀ /1.0 mL	≤10 ^{1.5}	---	TCID ₅₀ /1.0 mL
485552-52	Herpes simplex virus type 1	10 ⁻¹ to 10 ⁻⁸ dilutions	Complete inactivation	Complete inactivation	10 ^{6.0}
		TCID ₅₀ /0.1 mL	≤10 ^{0.5}	≤10 ^{0.5}	TCID ₅₀ /0.1 mL
485552-53	Herpes simplex virus type 2	10 ⁻¹ to 10 ⁻⁷ dilutions	Complete inactivation	Complete inactivation	10 ^{4.75}
		TCID ₅₀ /0.1 mL	≤10 ^{0.5}	≤10 ^{0.5}	TCID ₅₀ /0.1 mL
485552-54	Human immunodeficiency virus type 1	10 ⁻¹ to 10 ⁻⁷ dilutions	Complete inactivation	Complete inactivation	10 ^{5.25}
		TCID ₅₀ /0.2 mL	≤10 ^{0.5}	≤10 ^{0.5}	TCID ₅₀ /0.2 mL
485552-55	Infectious laryngotracheitis	10 ⁻¹ to 10 ⁻⁸ dilutions	Complete inactivation	Complete inactivation	10 ^{5.0}
		TCID ₅₀ /0.1 mL	≤10 ^{0.5}	≤10 ^{0.5}	TCID ₅₀ /0.1 mL
485552-56	Newcastle disease virus	10 ⁻¹ to 10 ⁻⁸ dilutions	Complete inactivation	Complete inactivation	10 ^{5.75}
		TCID ₅₀ /0.1 mL	≤10 ^{0.5}	≤10 ^{0.5}	TCID ₅₀ /0.1 mL
	Porcine rotavirus	10 ⁻¹ to 10 ⁻⁸	Complete	Complete	>10 ^{8.5}

MRID Number	Organism	Results			Dried Virus Count
			Lot No. B	Lot No. C	
485552-57		dilutions	inactivation	inactivation	TCID ₅₀ /0.1 mL
		TCID ₅₀ /0.1 mL	≤10 ^{0.5}	≤10 ^{0.5}	
485552-58	Porcine Respiratory & Reproductive Syndrome virus	10 ⁻¹ to 10 ⁻⁸ dilutions	Complete inactivation	Complete inactivation	10 ^{5.75} TCID ₅₀ /0.1 mL
		TCID ₅₀ /0.1 mL	≤10 ^{0.5}	≤10 ^{0.5}	
485552-59	Pseudorabies	10 ⁻¹ to 10 ⁻⁸ dilutions	Complete inactivation	Complete inactivation	10 ^{6.5} TCID ₅₀ /0.1 mL
		TCID ₅₀ /0.1 mL	≤10 ^{0.5}	≤10 ^{0.5}	
485552-60	Transmissible gastroenteritis	10 ⁻¹ to 10 ⁻⁸ dilutions	Complete inactivation	Complete inactivation	10 ^{4.5} TCID ₅₀ /0.1 mL
		TCID ₅₀ /0.1 mL	≤10 ^{0.5}	≤10 ^{0.5}	
485552-61	Vesicular stomatitis	10 ⁻¹ to 10 ⁻⁸ dilutions	Complete inactivation	Complete inactivation	10 ^{6.0} TCID ₅₀ /0.1 mL
		TCID ₅₀ /0.1 mL	≤10 ^{0.5}	≤10 ^{0.5}	

MRID Number	Organism	Lot No.	Average No. Surviving	Microbes Initially Present	Percent Reduction
			(CFU/mL)		
30-Second Exposure Time at a 1:768 Dilution					
485552-30	<i>Aeromonas hydrophila</i>	B	1 x 10 ¹	7.6 x 10 ⁷	>99.999
		C	1 x 10 ¹	7.6 x 10 ⁷	>99.999
485552-31	<i>Clostridium perfringens</i>	B	<1 x 10 ¹	8.0 x 10 ⁷	>99.999
		C	<1 x 10 ¹	8.0 x 10 ⁷	>99.999
485552-32	<i>Escherichia coli</i>	A	3.6 x 10 ²	8.2 x 10 ⁷	>99.999
		B	<1 x 10 ¹	8.2 x 10 ⁷	>99.999
		C	6 x 10 ¹	8.2 x 10 ⁷	>99.999
485552-33	<i>Escherichia coli</i> O157:H7	B	<1 x 10 ¹	9.4 x 10 ⁷	>99.999
		C	<1 x 10 ¹	9.4 x 10 ⁷	>99.999
485552-34	<i>Escherichia coli</i> O111:H8	B	<1 x 10 ¹	7.7 x 10 ⁷	>99.999
		C	<1 x 10 ¹	7.7 x 10 ⁷	>99.999
485552-35	<i>Enterobacter sakazakii</i>	B	<1 x 10 ¹	1.03 x 10 ⁸	>99.999
		C	<1 x 10 ¹	1.03 x 10 ⁸	>99.999
485552-36	<i>Klebsiella pneumoniae</i>	B	<1 x 10 ¹	1.20 x 10 ⁸	>99.999
		C	<1 x 10 ¹	1.20 x 10 ⁸	>99.999
485552-37	<i>Shigella dysenteriae</i>	B	<1 x 10 ¹	8.1 x 10 ⁷	>99.999
		C	<1 x 10 ¹	8.1 x 10 ⁷	>99.999
485552-38	<i>Salmonella enterica</i>	B	<1 x 10 ¹	1.17 x 10 ⁸	>99.999
		C	<1 x 10 ¹	1.17 x 10 ⁸	>99.999
485552-39	<i>Shigella sonnei</i>	B	<1 x 10 ¹	1.05 x 10 ⁸	>99.999
		C	<1 x 10 ¹	1.05 x 10 ⁸	>99.999
485552-40	<i>Salmonella typhi</i>	B	<1 x 10 ¹	8.5 x 10 ⁷	>99.999
		C	<1 x 10 ¹	8.5 x 10 ⁷	>99.999
485552-44	<i>Yersinia enterocolitica</i>	B	<1 x 10 ¹	1.08 x 10 ⁸	>99.999
		C	<1 x 10 ¹	1.08 x 10 ⁸	>99.999
30-Second Exposure Time at a 1:384 Dilution					

MRID Number	Organism	Lot No.	Average No. Surviving	Microbes Initially Present	Percent Reduction
			(CFU/mL)		
485552-41	<i>Staphylococcus aureus</i>	A	<1 x 10 ¹	1.18 x 10 ⁸	>99.999
485552-42	<i>Staphylococcus aureus</i>	B	<1 x 10 ¹	1.18 x 10 ⁸	>99.999
485552-43	<i>Staphylococcus aureus</i>	C	<1 x 10 ¹	1.18 x 10 ⁸	>99.999

VI. CONCLUSION

1. The submitted efficacy data **support** the use of a 1:427 dilution of the product, Maguard 5626, as a disinfectant with bactericidal and fungicidal activity against the following microorganisms on hard, non-porous surfaces in the presence of 400 ppm hard water and a 5% organic soil load for a 10-minute contact time:

<i>Staphylococcus aureus</i>	MRID 485552-09 through -11
<i>Salmonella enterica</i>	MRID 485552-12 through -14
Vancomycin Resistant <i>Enterococcus faecalis</i>	MRID 485552-18
Vancomycin Intermediate Resistant <i>Staphylococcus aureus</i>	MRID 485552-19
<i>Bordetella bronchiseptica</i>	MRID 485552-21
<i>Corynebacterium ammoniagenes</i>	MRID 485552-22
<i>Listeria monocytogenes</i>	MRID 485552-25
<i>Shigella sonnei</i>	MRID 485552-26
<i>Salmonella typhi</i>	MRID 485552-27
<i>Escherichia coli</i> O157:H7	MRID 485552-28
<i>Trichophyton mentagrophytes</i>	MRID 485552-29

Acceptable killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. In testing against *Staphylococcus aureus* and *Salmonella enterica*, at least one of the product lots tested was at least 60 days old at the time of testing. Neutralization confirmation testing showed positive growth of the microorganisms. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

2. The submitted efficacy data **support** the use of a 1:320 dilution of the product, Maguard 5626, as a disinfectant with bactericidal activity against the following microorganisms on hard, non-porous surfaces in the presence of 400 ppm hard water and a 5% organic soil load for a 10-minute contact time:

<i>Pseudomonas aeruginosa</i>	MRID 485552-15 through -17
Community Acquired Methicillin Resistant <i>Staphylococcus aureus</i>	MRID 485552-20
<i>Campylobacter jejuni</i>	MRID 485552-23
<i>Klebsiella pneumoniae</i>	MRID 485552-24

Acceptable killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. In testing against *Pseudomonas aeruginosa*, at least one of the product lots tested was at least 60 days old at the time of testing. Neutralization confirmation testing showed positive growth of the microorganisms. Neutralization confirmation testing for *Campylobacter jejuni* met the acceptance criterion of growth within 1 log₁₀ of the numbers control. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

3. The submitted efficacy data **support** the use of a 1:427 dilution of the product, Maguard 5626, as a disinfectant with virucidal activity against the following microorganisms on hard, non-porous surfaces in the presence of 400 ppm hard water and a 5% organic soil load (a 100% organic load against Duck hepatitis B virus) for a 10-minute contact time:

Avian adenovirus	MRID 485552-45
Avian influenza A (H5N1) virus	MRID 485552-46
Avian infectious bronchitis virus	MRID 485552-47
Infectious bursal disease	MRID 485552-48
Human coronavirus	MRID 485552-49
Duck hepatitis B virus	MRID 485552-50 and -51
Herpes simplex virus type 1	MRID 485552-52
Herpes simplex virus type 2	MRID 485552-53
Human immunodeficiency virus type 1	MRID 485552-54
Infectious laryngotracheitis	MRID 485552-55
Newcastle disease virus	MRID 485552-56
Porcine rotavirus	MRID 485552-57
Porcine Respiratory & Reproductive Syndrome virus	MRID 485552-58
Pseudorabies	MRID 485552-59
Transmissible gastroenteritis	MRID 485552-60
Vesicular stomatitis	MRID 485552-61

Recoverable virus titers of at least 10⁴ were achieved. Cytotoxicity (or toxicity) was not observed. Complete inactivation (no growth) was indicated in all dilutions tested. In studies against Duck hepatitis B virus, the initial and confirmatory studies were performed at the same laboratory but under the direction of different study directors. Both the initial and confirmatory studies tested two replicates per product lot. The confirmatory study tested one product lot, not the standard two product lots.

4. The submitted efficacy data **support** the use of a 1:768 dilution of the product, Maguard 5626, as a sanitizing rinse against the following microorganisms on pre-cleaned, hard, non-porous, food contact surfaces in the presence of 500 ppm hard water for a 30-second contact time:

<i>Aeromonas hydrophila</i>	MRID 485552-30
<i>Clostridium perfringens</i>	MRID 485552-31
<i>Escherichia coli</i>	MRID 485552-32
<i>Escherichia coli</i> O157:H7	MRID 485552-33
<i>Escherichia coli</i> O111:H8	MRID 485552-34
<i>Enterobacter sakazakii</i>	MRID 485552-35
<i>Klebsiella pneumoniae</i>	MRID 485552-36
<i>Shigella dysenteriae</i>	MRID 485552-37
<i>Salmonella enterica</i>	MRID 485552-38

Shigella sonnei
Salmonella typhi
Yersinia enterocolitica

MRID 485552-39
MRID 485552-40
MRID 485552-44

Bacterial reductions of at least 99.999 percent were observed within 30 seconds. Neutralization confirmation testing met the acceptance criterion of growth within 1.0 log₁₀ of the numbers control. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

5. The submitted efficacy data (MRID 485552-41, -42, -43) **support** the use of a 1:384 dilution of the product, Maguard 5626, as a sanitizing rinse against *Staphylococcus aureus* on pre-cleaned, hard, non-porous, food contact surfaces in the presence of 500 ppm hard water for a 30-second contact time. Bacterial reductions of at least 99.999 percent were observed within 30 seconds. At least one of the product lots tested was at least 60 days old at the time of testing. Neutralization confirmation testing met the acceptance criterion of growth within 1.0 log₁₀ of the numbers control. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

VII. LABEL

1. The proposed label claims that a 1:320 dilution of the product, Maguard 5626, is an effective disinfectant against the following microorganisms on hard, non-porous surfaces in the presence of 400 ppm hard water and 5% blood serum for a 10-minute contact time:

Pseudomonas aeruginosa
Salmonella enterica
Staphylococcus aureus

Bordetella bronchiseptica
Campylobacter jejuni
Community Acquired Methicillin Resistant *Staphylococcus aureus* (NRS 5123, USA400)
Corynebacterium ammoniagenes
Vancomycin Resistant *Enterococcus faecalis*
Escherichia coli O157:H7
Klebsiella pneumoniae
Listeria monocytogenes
Salmonella typhi
Shigella sonnei
Vancomycin Intermediate Resistant *Staphylococcus aureus*

These claims are acceptable as they are supported by the submitted data.

2. The proposed label claims that a 1:320 dilution of the product, Maguard 5626, is an effective disinfectant against Methicillin Resistant *Staphylococcus aureus* (ATCC 33591) on hard, non-porous surfaces in the presence of 400 ppm hard water and 5% blood serum for a 10-minute contact time. **Data were not provided to support this claim. References to Methicillin Resistant *Staphylococcus aureus* must be deleted from the proposed label.**

3. The proposed label claims that a 1:427 dilution of the product, Maguard 5626, is an effective disinfectant against the following microorganisms on hard, non-porous surfaces in the presence of 400 ppm hard water and 5% blood serum for a 10-minute contact time:

Salmonella enterica
Staphylococcus aureus

Bordetella bronchiseptica
Corynebacterium ammoniagenes
Vancomycin Resistant *Enterococcus faecalis*
Escherichia coli O157:H7
Listeria monocytogenes
Salmonella typhi
Shigella sonnei
Vancomycin Intermediate Resistant *Staphylococcus aureus*

Trichophyton mentagrophytes

Avian adenovirus
Avian infectious bronchitis virus
Avian influenza A (H5N1) virus
Influenza A virus (H1N1)
Hepatitis B virus
Herpes simplex type 1 virus
Herpes simplex type 2 virus
Human immunodeficiency virus type 1
Human coronavirus
Infectious bursal disease
Infectious laryngotracheitis

Newcastle disease virus
Porcine Respiratory & Reproductive Syndrome virus
Porcine rotavirus
Pseudorabies
Transmissible gastroenteritis
Vesicular stomatitis

These claims are acceptable as they are supported by the submitted data.

4. The proposed label claims that a 1:768 dilution of the product, Maguard 5626, is an effective sanitizing rinse against the following microorganisms on pre-cleaned, hard, non-porous, food contact surfaces in the presence of 400 ppm hard water for a 30-second contact time:

Aeromonas hydrophila
Clostridium perfringens - vegetative
Enterobacter sakazakii
Escherichia coli
Escherichia coli O111:H8
Escherichia coli O157:H7
Klebsiella pneumoniae
Salmonella enterica

Salmonella typhi
Shigella dysenteriae
Shigella sonnei
Yersinia enterocolitica

These claims are acceptable as they are supported by the submitted data.

5. The proposed label claims that a 1:768 dilution of the product, Maguard 5626, is an effective sanitizing rinse against *Staphylococcus aureus* on pre-cleaned, hard, non-porous, food contact surfaces in the presence of 400 ppm hard water for a 30-second contact time. **Data were not provided to support this claim. Efficacy testing against *Staphylococcus aureus* was conducted using a more concentrated use solution (i.e., a 1:384 dilution) of the product.**

6. The proposed label claims that a 1:768 dilution of the product, Maguard 5626, is an effective sanitizing rinse against *Salmonella enteritidis* on pre-cleaned, hard, non-porous, food contact surfaces in the presence of 400 ppm hard water for a 30-second contact time. **Data were not provided to support this claim. References to *Salmonella enteritidis* must be deleted from the proposed label.**

7. The following revisions must be made to the proposed label:

- On page 3 of the proposed label (left column), change "ATCC 9361" to read "ATCC 11835."
- On page 4 of the proposed label (left column) under the "Booster for Alkaline Detergents ..." section, **correct the parenthetical** "(of water?)."
- On page 4 of the proposed label (right column), change "tile" to read "**glazed tile.**" Tile is a porous surface.
- On page 5 of the proposed label (left column), change "*Escherichia coli* 0157:H7" to read "*Escherichia coli* O157:H7."
- On page 5 of the proposed label (left column), change "NRS 5123" to read "NRS 123."
- On page 5 of the proposed label (left column), change "ATCC 105800" to read "ATCC 10580."
- On page 5 of the proposed label (left column), change "ATCC VR260" to read "ATCC VR733."

Note: Registrant may change product name from "Maguard 5626" to "Maguard 5927" since active ingredients concentration have changed from 5.6 and 26.5 to 5.9 and 27.3 respectively.

Note: OPPIN record of the product Maguard 5626 must reflect AIs concentrations of 5.9% and 27.3%.